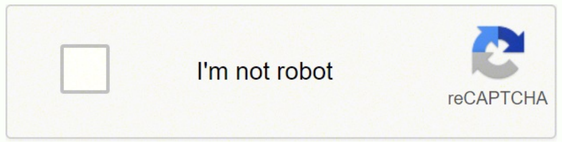

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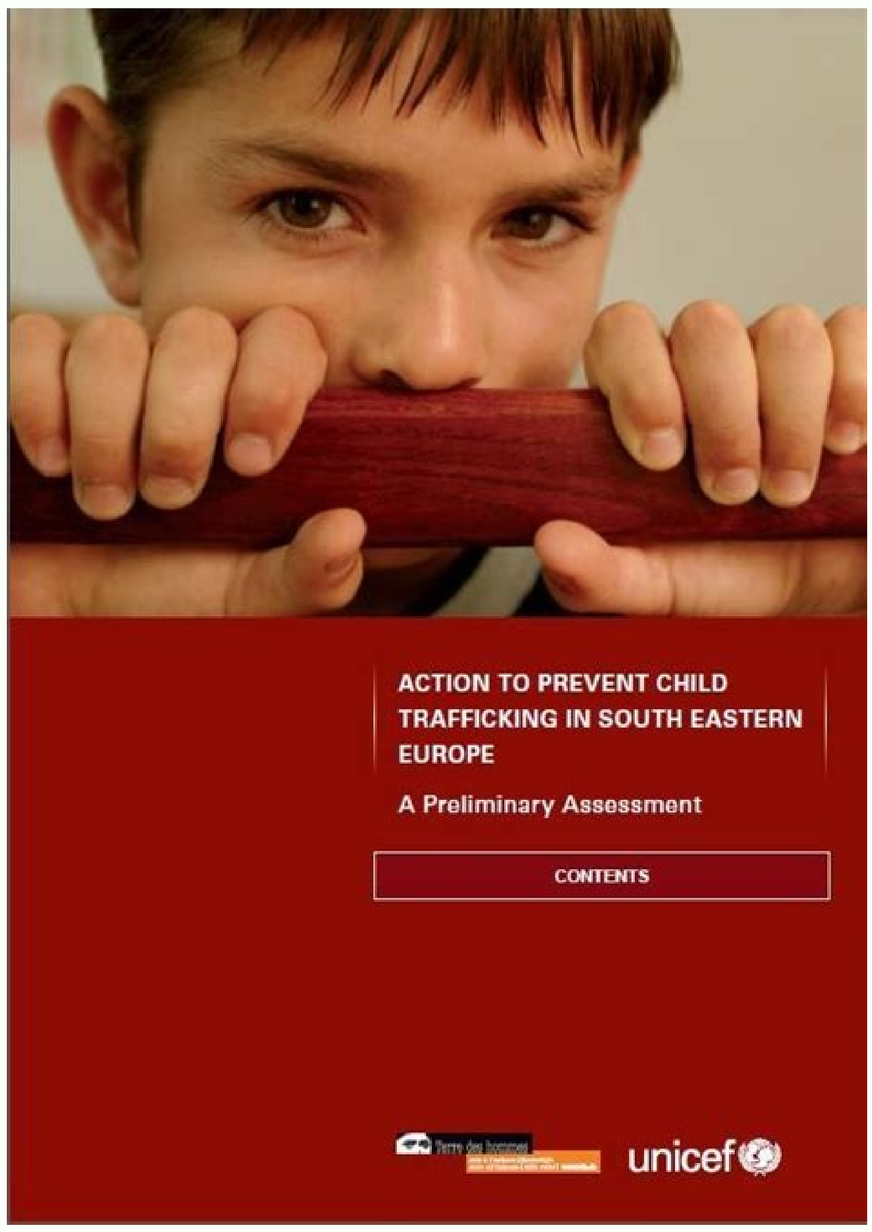
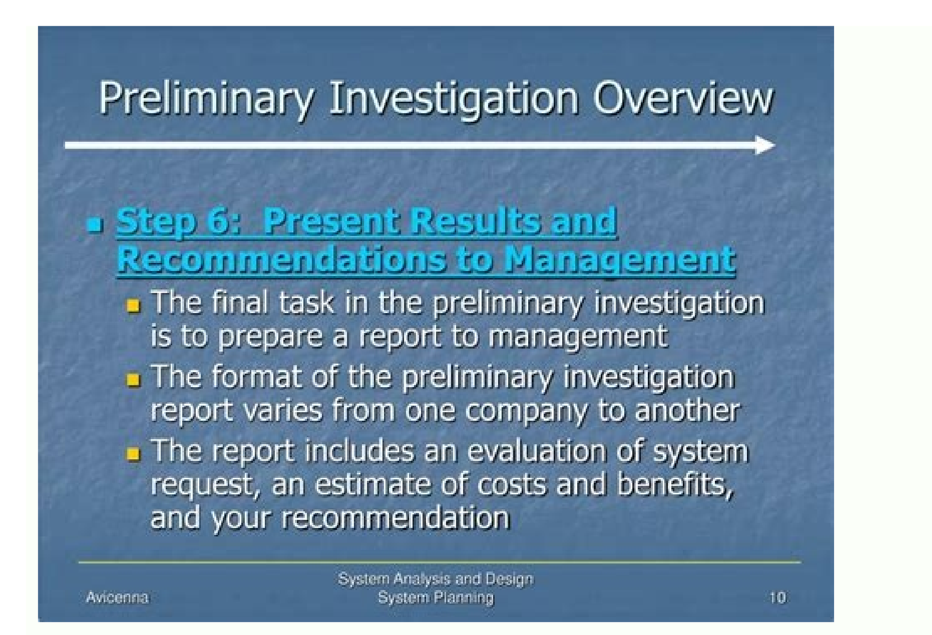
Preliminary findings and recommendations report

OTHER PARTS OF REPORT

- Bibliography
  - list of references for sources cited in the report
  - use APA referencing style
- Appendices
  - clean copy of the survey questionnaire
  - manual collation
  - list of interview questions (if any)





What is findings and recommendations. What to look for in a preliminary title report. How to read a preliminary report. How to write a report with findings and recommendations.

Available at . Seattle WA: Washington State Department of Health. The remaining testing sites (22%) have PPMP certificates, meaning that in addition to waived tests, direct microscopic examinations of certain specimens can be performed as part of the patient's examination by that patient's physician or midlevel health-care practitioner. For CW testing personnel, according to the CMS data, the top four categories were nurses (46%), medical assistants (25%), physicians (9%), and high school graduates (7%) (Table 3). Steindel SJ, Granade S, Lee J, et al. The New York Sentinel Network (NYSN) consisted of approximately 600 limited service laboratories (facilities other than physician office laboratories [POLs] that perform only waived tests and PPMP). The product insert should provide information on procedures for handling unexpected control results, identifying sources of error (including interfering substances), and manufacturer contact information for technical assistance. Bernhardt, PhD, Director; and the Division of Public Health Partnerships, Robert Martin, DrPH, Director. Because surveying all CW sites is not feasible, the proposed actions to improve and promote quality testing in CW sites emphasize the importance of education and training for CW site directors and testing personnel. Test system considerations --- Consider the simplicity of operating the test system, length of time to obtain a result, and the level of technical support provided by the manufacturer or distributor. Information for this evaluation can be obtained from the test manufacturer's product insert (Table 7) or by speaking with the manufacturer's technical representatives. The CW site director or other person responsible for overseeing testing should ensure that testing personnel receive adequate training and are competent to perform the procedures for which they are responsible. A valid CLIA certificate is required for Medicare reimbursement. This trend is expected to continue as laboratory testing technology continues to evolve. Clin Chem 1996;42:813--6. Results can be recorded directly in a patient's chart, in log books, or on a separate report form. Specimen collection. They also address developing procedures and training CW personnel and describe recommended practices for each phase of the total testing process, or path of workflow, including the important steps or activities before, during, and after testing. The recommendations provided in this report are intended to serve as a guide to improve the quality of testing in CW sites and enhance patient safety. Specimen Collection and Handling The product insert provides details on proper collection, handling, and storage of patient specimens. Inside the physician office laboratory: keeping waived tests simple. Although study findings indicate CW sites generally take measures to perform testing correctly, they raise quality concerns about practices that could lead to errors in testing and poor patient outcomes. When nonwaived confirmatory testing is needed, the patient can be sent to another facility for specimen collection and testing, or the specimen can be collected at the CW site and sent to a referral laboratory. Specimen labeling. Assessment activities should be conducted in a positive manner with an emphasis on education and promoting good testing practices. Users should not rely on this HTML document, but are referred to the electronic PDF version and/or the original MMWR paper copy for the official text, figures, and tables. Each CW site must comply with OSHA standards pertinent to workplace hazards (23). The data collected from these surveys, along with data on waived testing practices gathered through CDC-funded studies conducted during 1999--2003 by the state health departments of Arkansas, New York, and Washington (collectively referred to as the Laboratory Medicine Sentinel Monitoring Network [LMSMN]), support the initial CMS findings of gaps in good laboratory practices in these sites (11--16). Arch Pathol Lab Med 2002;126:1471--5. Selecting and evaluating a referral laboratory; approved guideline. Management Responsibility Each testing site should identify at least one person responsible for testing oversight and decision-making, later referred to as the CW site director. LaBeau KM, Simon M, Steindel SJ. State health departments or other government agencies that can provide limited training. Laboratory Requirements, 42 C.F.R. Chapter IV, Part 493 (2003). In addition, a 2001 report issued by the HHS Office of Inspector General (OIG), following their investigation of CLIA certification and enrollment processes, identified the lack of routine on-site visits to CW sites by surveyors representing state agencies and private sector accreditation organizations as presenting vulnerabilities in these sites. Logs and other records should have sufficient information to track and retrieve the test results and reports, such as: Information linking the referred specimen to patient identification, The name and contact information for the referral laboratory, The test name and date referred, Complete test results and the date received, and The date the final report is issued. Additional information on HIPAA is available at . When state or local regulations governing laboratory testing are more stringent than the federal CLIA requirements, they supersede what is required under CLIA. The person responsible for testing oversight should ensure that all state and local requirements are met. For those children and their families who need additional care, we are recommending changes to the mental health system to make sure that there are better links between services and that the right services are available at the right time, regardless of how people enter the system. Available at . Members: Kimberle C. Neglecting to follow instructions could cause inaccurate test results that could lead to incorrect diagnoses, inappropriate or unnecessary medical treatment, and poor patient outcomes. Regulatory requirements. They are intended to be used by those who would benefit from improving their knowledge of good laboratory practices. On the basis of manufacturer's instructions, 21% of the CW sites did not perform QC testing as specified, and 18% of the sites did not use correct terminology or units of measure when reporting results. External Assessment Because CW sites are not routinely inspected by CMS, voluntary inspections by peers or consultants can offer additional educational opportunities and feedback on current practices along with ideas for quality improvement. URL addresses listed in MMWR were current as of the date of publication. Temperature --- Temperature ranges for storage of test components and controls and for test performance are defined by the manufacturer to maintain test integrity. Safety requirements. Occupational Safety and Health Administration. The requirements for compliance with this standard include, but are not limited to: A written plan for exposure control, including postexposure evaluation and follow-up for the employee in the event of an "exposure incident;" Use of Universal Precautions, an approach to infection control in which all human blood and certain human body fluids are treated as if known to be infectious for HIV, hepatitis B virus, hepatitis C virus, and other bloodborne pathogens. When determining the frequency for running external controls, consider the robustness of the test, stability of the environment, and skills and knowledge of the testing personnel. Enrollment and certification processes in the clinical laboratory improvement amendments program. First, the CMS surveys were not intended to be a scientific study of a random sample of CW sites. Findings from the LMSMN studies were similar to the CMS findings for these quality deficiencies (11). In POLs, this might be a physician or someone in a senior management position who has the appropriate background and knowledge to make decisions about laboratory testing. Clin Leadersh Manag Rev 2004;18:342--8. Quality Control Testing Performing QC testing procedures provides assurance that the test performs as expected and alerts the user when problems occur. Performance characteristics --- Assess the information on performance provided by the test manufacturer or published data. Arch Pathol Lab Med 2000;124:1201--8. Biohazard Waste Disposal Dispose of the biohazardous waste generated in specimen collection and testing according to site procedures that need to be in compliance with local ordinances, state, and federal OSHA regulations as previously discussed. Competency Assessment To ensure testing procedures are performed consistently and accurately, periodic evaluation of competency is recommended, with retraining, as needed, on the basis of results of the competency assessment (32). The Pacific northwest laboratory medicine sentinel monitoring network: inventory of CLIA-waived tests performed in Washington State. Standing orders for certain tests might apply, but they should be documented. Privacy and confidentiality requirements. Disclaimer All MMWR HTML versions of articles are electronic conversions from ASCII text into HTML. Although by law waived tests should have insignificant risk for erroneous results, these tests are not completely error-proof and are not always used in settings that employ a systems approach to quality and patient safety. LaBeau KM, Simon M, Granade S, Steindel SJ. The workgroup's findings were presented to CLIAC for its deliberations at the February 2005 meeting, at which time CLIAC provided recommendations to HHS concerning good laboratory practices for waived testing sites. Quantitative results can be obtained that are beyond the measuring range of the instrument or test device. GP21-A2) 2004. 1910.1030 (2001). Although training was provided before the surveys were conducted, the intent of the survey questions was subject to individual interpretation. The lack of oversight and requirements for personnel qualifications and training for an increasingly large number of CW sites is a concern and could contribute to errors and patient harm. Suggestions for helping to ensure correct timing of tests include using timers that beep until turned off, using timers that can easily be worn or attached to clothing, using multiple timers when performing more than one test at a time, and maintaining extra timers and batteries. If a chemical agent or anticoagulant is added to a blood specimen to prevent clotting, the specimen can be separated by centrifugation into cells and plasma PNWSN Pacific Northwest Sentinel Network POL physician office laboratory PPE personal protective equipment; specialized clothing or equipment worn by an employee for protection against a hazard PPMP provider-performed microscopy procedures; a subcategory of moderate complexity testing under CLIA precision reproducibility; the measure of the closeness of the results obtained when analyzing the same sample more than once; the measure of agreement between replicate measurements of the same material procedure manual a handbook that contains test methods and other information needed to perform testing product insert written product information usually supplied by the manufacturer with each test kit or test system containing instructions and critical details for performing the test; also referred to as package insert PT proficiency testing; an external quality assessment program in which samples are periodically sent to testing sites for analysis qualitative test a test that detects whether a particular analyte, constituent, or condition is present or absent quality assessment a group of activities to monitor and evaluate the CW site's entire testing process to help ensure that test results are reliable, improve the testing process, and promote good quality testing practices QC quality control; the procedures used to detect and correct errors that occur because of test system failure, adverse environmental conditions and variance in operator performance, as well as the monitoring of the accuracy and precision of the test performance over time quantitative test a test that measures the concentration or amount of an analyte in a specimen, whose results are expressed numerically quick reference instructions cards or small signs containing diagrams or flow charts with essential steps for conducting a test that are often included with waived test systems reactive or R a result that indicates the presence of the constituent that the test is designed to detect reagent a substance that produces a chemical or biological reaction with a patient specimen that allows detection or measurement of the analyte for which the test is designed reference interval the range of test values expected for a designated population of persons (e.g., 95% of persons presumed to be healthy [or normal]) referral laboratory a laboratory that receives specimens from CW sites to perform additional testing, often for follow-up confirmatory testing; the majority of referral laboratories perform nonwaived testing reportable range the span of test result values for which the instrument or test device can accurately measure sensitivity the lowest concentration of an analyte that can reliably be detected or measured by a test system serum the cell-free liquid remaining after whole blood has clotted or coagulated specificity the ability of a test to detect a particular substance or constituent without interference or false reactions by other substances Standard Precautions an approach used in healt-care settings to reduce the risk for transmission of microorganisms from both recognized and unrecognized sources of infection in a wide variety of human sources. Additional safety practices for performing testing are: Prohibit eating, drinking, or applying makeup in areas where specimens are collected and where testing is being performed (i.e., where hand-to-mouth transmission of pathogens can occur); Prohibit storage of food in refrigerators where testing supplies or specimens are stored; Provide hand-washing facilities or antiseptic hand-washing solutions; and Post safety information for employees and patients. State and local jurisdictions often regulate biohazard safety, including handling and disposal of medical waste. MMWR 1988;37:377--82, 387--8. Finally, the CMS surveys did not assess the frequency of erroneous test results in CW sites or whether lapses in following manufacturers' instructions directly affected test results or patient outcomes. Collect waived test specimens exactly as described in the test system instructions, using the appropriate collection device and method to obtain a quality specimen (33--36). Test results contribute to diagnosis and prognosis of disease, monitoring of treatment and health status, and population screening for disease. National inventory of clinical laboratory testing services (NICLTS): development and test distribution for 1996. The test site should have telephone numbers or other contact information readily available (e.g., numbers for manufacturers' technical assistance, the facility's director, consultant, or public health departments). Additional safety and biohazard equipment. This form asks for specific information, including the type of testing site (laboratory type), hours of operation, estimated total annual volume of waived testing, and the total number of persons involved in performing waived testing. Test Orders, Patient Identification, and Preparation Before collecting the specimen, confirm the test(s) ordered and the patient's identification and verify that pretest instructions or information, as applicable, have been provided. H03-A5) 2003. How much training will be needed? Good laboratory practices include recording what happens, whether acceptable or not, and what is done to correct problems encountered during testing. Corrective action when control testing fails. --- Be aware that temporary or parttime personnel might be less proficient in performing testing. PNWSN and ASN gathered data about waived testing practices through questionnaires mailed to network members (11). In addition, the 2002--2004 CMS survey findings resulted in the same general conclusions as the earlier CMS pilot studies, which were conducted on a random sample of laboratories (10). Testing space and facilities. Table 1Return to top. Controls should be tested either before or concurrent with patient specimens by the same personnel who routinely perform patient testing. Among the top categories of testing personnel in the PNWSN, turnover rates were highest for medical assistants (17%), followed by LPNs (13%), RNs (9%), and physicians (2%) (14). Table 4Return to top. Waived testing sites, such as point-of-care sites or physicians' offices, might accurately and legibly record results directly in the patient's record as a matter of practice. External controls --- mimic patient specimens and monitor the testing process, from specimen application to result interpretation, to assure proper test performance. This section describes factors to consider before opening a waived testing site or offering an additional waived test. LaBeau KM, Granade S. Wayne, PA: NCCLS; (publication no. The activities that occur in each of these phases are critical to providing quality testing (Table 6). Uninformed personnel might mistakenly use a promotional test kit, provided by a distributor or manufacturer's representative, for patient testing without realizing the consequences of test substitution. Initial teacher education and professional development programs should be accredited using nationally consistent guidelines (action 5.3), and ongoing learning about child social and emotional development and wellbeing should form part of the ongoing professional development requirements for all teachers (action 5.4). Quick reference instructions should be clearly posted where testing is performed. Benefits and costs. Atlanta, GA: CDC; 1998. Testing records should be maintained in chronological order to facilitate retrieval of information if needed. External quality assessment or evaluation programs, such as voluntary PT programs, are another resource for assessment. In addition, CW sites should be aware that applicable state laws that provide more stringent privacy protections for patients supersede HIPAA. CLIAC Response An initial CMS report of its 2002--2003 survey findings, presented to CLIAC in 2004, supported earlier concerns about the quality of testing practices and the need for education and training of testing personnel in CW sites. Available at . Trained laboratorians (i.e., medical technologists and medical laboratory technicians) accounted for 2% of laboratory directors and testing personnel in the CW sites surveyed by CMS and a smaller percentage in the limited service laboratories surveyed by the NYSN (13). Summary Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), simple, low-risk tests can be waived and performed with no routine regulatory oversight in physicians' offices and various other locations. Ex Officio Representatives: Steven I. CMS surveys indicated that 45% of CW sites did not document the name, lot number, and expiration dates for tests performed; 35% did not maintain logs with records of their QC testing; 31% did not maintain a log or record of tests performed; and 9% did not require a requisition or test orders documented in a patient chart before performing a test (Table 5). Anonymous. They are designed to verify that the test system is working as expected, that sufficient specimen was added and, for unitized test devices, whether it migrated through the test strip properly. Another PNWSN study indicated that most training (77%) took place in a day or less (14). Clinical laboratory technical procedure manuals; approved guideline, 4th ed GP02-A4. Surveys conducted during 1999--2004 by the Centers for Medicare & Medicaid Services and studies funded by CDC during 1999--2003 evaluated testing practices in sites holding a CLIA Certificate of Waiver (CW). Collection devices. Contact GPO for current prices. However, in CW sites, most directors and testing personnel did not have formal laboratory training or testing experience, there was a high turnover of personnel, and lapses in following manufacturers' instructions and instituting practices to ensure the quality of the testing were noted. CLIA requirements that apply to testing sites operating under a CW include the following: Renew the CW every 2 years. Available at . Solomon, MD, Director; National Center for Health Marketing, Jay M. Personnel Considerations Personnel competency and turnover are important factors affecting the quality and reliability of waived testing results. Online services for student mental health should be expanded to meet student needs (action 6.1). An additional route to waiver exists through a process in which FDA evaluates studies and other information submitted by manufacturers to demonstrate that a test meets the waiver criteria of being simple and having a low risk for error. In addition, this report presents recommendations developed by the Clinical Laboratory Improvement Advisory Committee (CLIAC) for improving the quality of waived testing. In addition, certain manufacturers provide quick reference instructions formatted as cards or small signs containing essential steps in conducting a test. Professional organizations that can provide workshops or other training tools. Fact sheet: Children and young people (PDF - 544 Kb) Mental health underpins children's and young people's social and emotional development and their sense of wellbeing. One of the recommendations in the 2001 OIG report was that CMS should provide educational outreach to directors of waived and PPMP laboratories about the CLIA requirements (17). Washington, DC: US Department of Health and Human Services; 2001. To monitor how schools are supporting students of all ages over time, all schools should measure student wellbeing. CLIAC supported publication of the recommendations, along with the data from the studies of CW sites, and suggested the publication could serve as a comprehensive source document that could be used to develop additional educational tools appropriate for specific target audiences. Garrott, EdM, Clinical Laboratory Science Dept, University of Illinois at Springfield; Patrick A. MMWR Summary of notifiable diseases. A report issued in 1999 by the Institute of Medicine (IOM) presented a national agenda to address these issues and recommended strategies for change that included the implementation of safe practices at the health-care delivery level (7). Garrott, EdM, Clinical Laboratory Science Department, University of Illinois at Springfield, Illinois; Barbara M. Although the study results indicated that most testing personnel were trained, they were often trained for minimum periods by persons who did not have formal education or training in clinical laboratory testing and who might not have understood the importance of measures to ensure quality testing. Factors to consider include: Humidity --- Unusually high, low, or extreme fluctuations in humidity can cause deterioration of reagents and test components, affect the rate of chemical reactions and specimen interaction, or make test endpoints blurred and difficult to read. Changes to the timing of the test or physical alteration of the test components (e.g., cutting test cards or strips to increase the number of specimens tested per kit) are examples of modifications. We make a number of recommendations to better support the social and emotional wellbeing of children in schools and early childhood education and care by improving early identification of risk factors, and making the education system more effective in supporting their wellbeing. Regulatory Requirements CLIA certification. Assess the potential need for additional time, documentation, and staffing and a mechanism to refer additional testing to another laboratory when offering such tests. Bloodborne pathogens, 29 C.F.R., Sect. Recommended Good Laboratory Practices Overview These recommendations are intended to promote the use of good laboratory practices by physicians, nurses, and other providers of waived testing in a variety of CW sites. Scope of Waived Testing Sites performing only waived tests comprise 58% (105,138) of the approximately 180,000 laboratory testing sites in the United States (Table 1, Figure 1). Quality assurance guidelines for testing using the OraQuick rapid HIV-1 antibody test. Waived test specimens. waived test a test system, assay, or examination that has been cleared by the FDA for home use, or HHS has determined meets the CLIA criteria of being a simple test with an insignificant risk for an erroneous result whole blood blood containing all its cellular components that has not undergone centrifugation or had the plasma removed Clinical Laboratory Improvement Advisory Committee Workgroup Chair: Jared N. Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services.References to non-CDC sites on the Internet are provided as a service to MMWR readers and do not constitute or imply endorsement of these organizations or their programs by CDC or the U.S. Department of Health and Human Services. They might be provided as liquid or other materials similar to patient specimens and might be included with the test system or purchased separately. Executive Secretary: Robert Martin, DrPH, National Center for Health Marketing, CDC, Atlanta, Georgia. Unitized test system instructions usually suggest repeating the test with a new device and referring to QC or trouble-shooting procedures. Provide the patient with pretest instructions, when appropriate, and when special preparation is needed, verify that patients received instructions before testing. Conclusion This report summarizes the findings of multiple surveys of sites performing waived testing throughout the United States. Different facilities were surveyed each year so that no repetition exists among CW sites represented in the CMS data in this report. JAMA 2005; 293:2384--90. To avoid transmission of hepatitis B virus, hepatitis C virus, HIV, and other bloodborne pathogens, appropriately discard sharps, lancets, and platforms for spring-loaded lancets and disinfect instruments contaminated by blood (9, 28). Available at . These devices, whether supplied with the test system or specified in the product insert, are integral to the test system and should be used to ensure the correct specimen type and volume to provide reliable results. Even though the majority of CW sites meet the CLIA requirement to follow manufacturers' instructions for test performance, and many sites follow additional good laboratory practices, over the years these studies have demonstrated that a persistent percentage of CW sites do not meet minimal requirements and are not aware of recommended practices to help ensure quality testing. However, according to the CW sites that provided this information for 2003--2004 (Table 4), nurses most frequently provided waived test training (33%), followed by the manufacturer or sales representatives (15%). The time spent on training was not captured as part of the CMS surveys. Sales restrictions, such as special training requirements, development of a quality assurance program, or provision of information to patients, might apply to some waived tests and require additional planning and resources. Atlanta, GA: CDC. Log books or electronic systems can be used for maintaining and tracking information. The person collecting the patient specimen or giving the collection instructions should have a thorough understanding of the specimen type, proper collection method (including the need to wear gloves or other PPE as appropriate), and handling to assure a quality specimen (33--36). Reports should meet the needs of the testing site and should be appropriately standardized so reports generated on-site are easily distinguishable from referral laboratory reports. Although not among the most commonly performed, waived tests are available for certain infectious diseases of public health significance and were reportedly performed by CW sites in the CMS surveys (influenza, 46 sites; HIV, four; and Lyme disease, one). Time intervals longer than those specified in the product insert can result in false positive, false negative, or invalid results because of exaggerated color development, fading of reaction products, or migration beyond a visible range. Kandalaft, Provider Contracting & Provider Services Lovelace Health Systems, Inc., Albuquerque, New Mexico; Barbara E. Facilities performing only waived tests have no routine oversight and no personnel requirements and are only required to obtain a Certificate of Waiver (CW), pay biennial certificate fees, and follow manufacturers' test instructions. Personnel training, competency assessment, and the potential need for additional personnel. Williams, MD, Methodist Pathology Center, Nebraska Methodist Hospital, Omaha; Jean Amos Wilson, PhD, Focus Diagnostics, Inc., Cypress, California. Introduction Laboratory testing plays a critical role in health assessment, health care, and ultimately, the public's health. Hand hygiene should be performed between patients. Goldsmith, PhD, Caritas St. Elizabeth's Medical Center, Boston, Massachusetts; Luann Ochs, MS, Roche Diagnostics Corporation, Indianapolis, Indiana; Barbara E. When gloves are worn during specimen collection, they should be removed and discarded in an appropriate waste receptacle before contact with another patient. Although the exact volume of each test performed per site is not known, on the basis of the number of sites testing for each analyte, the five most commonly performed waived tests were identified as glucose, dipstick urinalysis, fecal occult blood, urine human chorionic gonadotropin (hCG) (visual color comparison), and group A streptococcal antigen (direct test from throat swabs) (Figure 3). Regulatory compliance. Table 2Return to top. Turner, DrPH, North Carolina State Laboratory of Public Health, Raleigh; Robin Weiner, Biosite Inc., San Diego, California; Thomas L.Williams, MD, Methodist Pathology Center, Nebraska Methodist Hospital, Omaha. To prevent errors, always label specimens with pertinent information (e.g., unique patient name or other unique identifier). The purpose of this report is to highlight quality issues identified in waived testing sites on the basis of surveys conducted on-site by the Centers for Medicare & Medicaid Services (CMS) during 1999--2004 and studies of waived testing practices funded through CDC during 1999--2003. Although the majority of CW sites in the CMS surveys (90%) reported that new personnel were trained, fewer sites (85%) evaluated staff to ensure competency. The testing procedures form the basis of training for testing personnel. Washington, DC: Occupational Safety and Health Administration; 2003. Alfisi, JD, Health Industry Distributors Association, Alexandria, Virginia; Kimberle C. This would place wellbeing on an even footing with academic progress and student engagement as an important goal that schools across all sectors of the education system must work towards, and report on their progress. The Pacific northwest laboratory medicine sentinel monitoring network: final report of the findings of questionnaire 1---waived and PPMP sites---training on waived test systems. Therefore, it is important to have a system established to read results during the correct timeframe, especially if conducting more than one test at a time. Corresponding author: Devery Howerton, PhD, National Center for Health Marketing, Coordinating Center for Health Information and Service; 4770 Buford Hwy NE, MS G-23, Atlanta, GA, 30341. Teachers should be supported to improve the social and emotional wellbeing of children. Available at . Exposure to blood: what healthcare personnel need to know. Quality microcollection. Equipment maintenance, such as repairs or preventive maintenance contracts. No CLIA requirements exist for waived testing personnel qualifications; however, applicable state or local personnel regulations must be met. Review data that includes the test's accuracy, precision, sensitivity, specificity, and interferences. LaBeau KM. Recommended Practices During Testing When the testing area is prepared and the specimen has been collected, the process continues to the testing phase. Table 3Return to top. As a result, during 2002--2004, CMS conducted nationwide on-site surveys of CW facilities to collect additional data that would provide an assessment of testing, promote good laboratory practices and encourage improvement through educational outreach, and make recommendations on the basis of cumulative survey findings. These advances have enabled more testing to be performed in emergency departments, hospital rooms, and physicians' offices and in nontraditional testing sites such as community counseling centers, pharmacies, nursing homes, ambulances, and health fairs. Manufacturers might provide or specify specimen collection devices. Improperly collected, stored, or compromised specimens should not be tested. Testing Practices The CMS surveys indicated that the majority of the CW sites were aware of and followed some practices for ensuring the accuracy and reliability of their testing. Supplemental or Confirmatory Testing The product insert should explain when supplemental testing is needed to confirm a waived test result or when the test is to be used as part of a multitest algorithm. When opening a new kit, check for notifications in the external labeling or special notices that might be included with product inserts or packaging. When preparing to perform testing, allow time for any refrigerated items, including reagents or patient specimens, to reach room temperature before testing, if specified in the product insert. The trainee performs the test while the trainer observes. If a test result is not acceptable or requires repeat testing (e.g., out of range or invalid), record the initial result, noting it was unacceptable, take steps necessary to resolve the problem, then record the correct result. To err is human: building a safer health system. Waived testing performed in these sites is often wellness testing, screening tests, or other critical testing that introduces a large population of persons into the health-care setting. --- Consider how testing personnel will maintain competency, especially when testing volume is low. AST4-A) 1999. CMS certificate of waiver and provider performed microscopy procedures pilot project final report. The committee consists of 20 members selected by the HHS secretary from authorities knowledgeable in the fields of laboratory medicine, pathology, public health, and clinical practice and includes consumer representatives and an industry liaison. The Pacific northwest laboratory medicine sentinel monitoring network: final report of the findings of questionnaire 5---waived and PPMP sites---testing personnel turnover. CMS surveys indicated that certain CW sites (5%) were performing testing more complex than waived testing without taking required measures to ensure quality. Figure 1Return to top. Each site should determine the appropriate control testing frequency for each test system and the frequency should not be less than specified in the product insert. Since CLIA was implemented, waived testing has steadily increased in the United States. No interpretation is necessary to read the result. The three categories of testing for CLIA purposes are waived, moderate complexity (including the provider-performed microscopy procedures [PPMP] subcategory), and high complexity. Gomatos, MD, Fort Lauderdale, Florida; Cyril Michael Hetsko, MD, Madison, Wisconsin; Anthony N. An increasing shift toward waived testing has resulted in a corresponding increase in health-care expenditures for this testing. Available at . The OSHA Bloodborne Pathogens Standard applies to sites where workers have potential occupational exposure to blood and infectious materials (25). The educational background and qualifications for directors and testing personnel at CW sites were collected as part of the CMS surveys and by LMSMN (PNWSN and NYSN). Continued surveillance and monitoring of waived testing performance is needed to determine the effectiveness of these recommendations on protecting and improving the public's health. Physical Requirements for Testing Testing should be performed in a separate designated area where adequate space to safely conduct testing and maintain patient privacy is available. In addition, when testing personnel were not evaluated to determine their competency level following training or on an ongoing basis, no assessment was conducted to determine whether the training was effective. The OIG report indicated that approximately half of the state respondents reported problems related to quality issues with the waived laboratories in their states (e.g., failure to follow manufacturers' instructions or failure to identify incorrect results and performing unauthorized testing) (17). This is a concern because the only CLIA requirement for performing waived testing is to follow the manufacturer's instructions. Similarly, 59% of the PNWSN CW site directors were physicians, with the remaining 41% having other backgrounds or degrees (12). Additional funding should be provided to help early childhood education and care services to support children's social and emotional development. A confirmatory test could be a different waived test (performed at the testing site or another CW site) or a nonwaived test performed by a CLIA-certified referral laboratory (37) (Table 11). Medical and dental offices: a guide to compliance with OSHA standards. Refer to the product insert for limitations for use in particular patient populations. Among other quality deficiencies identified were failure to adhere to proper expiration dates for the test system, reagents, or control materials (6%) and failure to adhere to the storage conditions as described in the product insert (3%). Protection of laboratory workers from occupationally acquired infections; approved guideline, 3rd ed. This includes: specific targets and nationally consistent measures of student wellbeing (action 5.3). Assessment activities can be either internal or external, depending on the needs, resources, and practices of the site. Before offering a new test, consider the level of reimbursement and factors that contribute to total test cost. Preventing needlestick injuries in health care settings. They also cover good laboratory practices for the three phases of testing: 1) before testing (test ordering and specimen collection), 2) during testing (control testing, test performance, and result interpretation and recording), and 3) after testing (result reporting, documentation, confirmatory testing, and biohazard waste disposal). CDC is not responsible for the content of pages found at these sites. Results are interpreted as positive/reactive, negative/nonreactive, or invalid. By law, CLIA regulations are based on a complexity model, with more complicated testing subject to more stringent requirements (6). The findings of the CMS and LMSMN studies are strikingly similar. Incorrect timing of these types of tests can give erroneous test results. Paying attention to test orders, properly identifying and preparing the patient, collecting a good quality specimen, and setting up the test system and testing area all contribute to reliable test results. Members: Jennifer M. NYSN collected its data through on-site surveys during which waived testing practices were assessed by surveyor observation and record reviews (11). Internal Assessment Objective internal assessment offers flexible, low-cost options for evaluating quality such as self-conducted inspections, supervisory review of documented problems that occur in the different phases of the testing process, review of QC documentation, and testing and reporting procedures. Oak Brook, IL: Joint Commission for International Patient Safety.; 2005. These recommendations include considerations before introducing waived testing, such as management responsibility for testing, regulatory requirements, safety, physical and environmental requirements, benefits and costs, staffing, and documentation. To provide a guide that can be adapted for use, either in part or as a whole, by persons or facilities considering the initiation of waived testing and personnel performing waived testing, CLIAC provided recommendations for good laboratory practices. In some cases, records might be part of the patient's medical chart. For example, instructions might specify one drop of capillary blood or include precautions to use the second drop of blood from a fingerstick rather than the first. In some instances, CW sites were determined to be performing testing that was an imminent and serious threat to the public's health because they were performing nonwaived testing in the absence of CLIA-required quality measures. Perspectives in disease prevention and health promotion update: universal precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus and other bloodborne pathogens in health-care settings. Investing in the mental health of children and young people delivers significant returns, for them, their family and the community. Participation in these types of programs can be used to evaluate overall testing performance and as a training or educational tool for testing personnel. Recommendations include: Identifying a resource person or expert (e.g., a consultant or manufacturer's technical representative), available either off-site or on-site, to answer questions and be of assistance. Perform only waived tests. Certain testing personnel also were self-trained. Surveyed CW testing sites also reported performing various other nonwaived tests (e.g., urine and throat cultures, Rh antigen testing, and the use of glucometers to perform diagnostic glucose tolerance testing [an intended use not specified in manufacturers' instructions]). Safe specimen transport or shipping information as necessary, including special packaging and shipping requirements for confirmatory or supplemental tests for infectious diseases (e.g., HIV). Of the facilities surveyed by CMS during 2003--2004 (2002 data not available), 90% reported that they performed no more than five different waived tests, and 99% performed no more than 10 different waived tests. GP9-A) 1998. The state agency will process the application and send an invoice for the registration fee. Kohn LT, Corrigan JM, Donaldson MS, eds. Some states and localities have specific regulations for testing, some require licensure of personnel who perform testing, and some have phlebotomy requirements. If modified, tests are no longer waived tests and become subject to the more stringent CLIA requirements for nonwaived testing. New testing procedures should be reviewed and signed by the CW site director before incorporating them into the procedure manual. Staffing. Specimens that are processed or manipulated by the user (e.g., serum or plasma) require centrifugation, dilution, extraction, or other preparation steps that require special training or instrumentation and are not appropriate for waived tests. As a result, a workgroup was appointed to consider practices associated with the waived testing process and their impact on the quality of waived testing. Wayne, PA: NCCLS; 2005 (publication no. Resources for training are available from various sources. Resolving Problems If a discrepancy is identified between the patient's test results and the clinical information or if the results are invalid or otherwise compromised, testing should be repeated. Telephone: 770-488-8126; Fax: 770-488-8275; Email: dhowerton@cdc.gov. In addition, training should include aspects of safety (including Universal Precautions) and QC. Foucar, MD, Department of Pathology, University of New Mexico, Albuquerque; Paula W. Documenting and monitoring control testing results provides an indication that the test was properly performed by the operator and the test system (reagents, instruments, or any components) performed as expected. Evaluate the test system, its intended use, performance characteristics, and the population to be tested when assessing whether to introduce waived testing or a new waived test. Schools should be able to apply for dedicated funding to strengthen their wellbeing policies (action 5.6). These recommendations address decisions that need to be made and steps to be taken as a facility begins offering waived testing or adds a new waived test. Test system instructions can change over time and CW sites sometimes switch test systems that could have different instructions. Because the phrasing of some questions differed slightly from 2002 to 2003--2004, in certain cases, the meanings of the questions also changed. Turner, DrPH, North Carolina State Laboratory of Public Health, Raleigh; Thomas L. A unitized device is used for a single test and must be discarded after testing. Good laboratory practices. Training resources. When performing nonwaived tests, surveyors noted that, in some instances, the sites were not meeting CLIA requirements for qualified personnel, QC, PT, or test system maintenance. Each site offering only waived testing that is not included under any other type of CLIA certificate must obtain a CLIA CW before testing patient specimens. Parents requiring support would also benefit from other recommendations made in the report (see 'Consumers and carers fact sheet' for more information). For assistance, please send e-mail to: mmwrq@cdc.gov. Written Test Procedures To comply with CLIA requirements and provide accurate testing, CW sites must adhere to the manufacturer's current testing instructions. Other examples include group A streptococcal antigen testing, which is waived only when performed on a throat swab and not when performed on a microbiology culture, and visual color comparison tests for hCG (pregnancy tests) using urine that are waived, whereas serum or plasma hCG tests are not waived. Performing the Test The following points are important to remember when performing the test: Follow the steps in the test procedure in the exact order described in the product insert. Chapin, MD, Department of Pathology, Rhode Island Hospital, Providence, Rhode Island; Joeline D. The mental health of parents affects the social and emotional wellbeing of their children. Table 10Return to top. Table 9Return to top. Documents and Records Documentation is essential to assure quality waived testing. For example, throat swab collection kits used with group A streptococcal antigen tests might look the same; however, they might be made from a variety of fibers or contain different materials that could interfere with the test or affect organism viability. In addition, some tests have specific environmental requirements described in the manufacturer's product insert that need to be met to ensure reliable test results. Although direct microscopic examinations can be conducted by a physician or midlevel health-care practitioner as part of a patient examination, testing must be conducted under a CLIA PPMP certificate. If controls do not perform as expected, patient testing should not be performed or results reported until the problem is identified and corrected. Records of control results should be periodically reviewed to detect shifts or changes in performance over time. Critical values are test results necessary for patient evaluation or treatment that require immediate notification to the clinician. Contributing factors included inadequate training in good laboratory practices and high turnover rates of testing personnel. MMWR 2005;54:220--3. In addition, these sites did not have adequate records of their testing activities, including test system procedures, training records, or other documentation. Liaison Representative: Luann Ochs, MS, Roche Diagnostics Corporation, Indianapolis, Indiana. CMS survey results also indicated that, in varying proportions, when CW sites had the current instructions, they did not follow critical steps in the testing process (e.g., performing QC testing, reporting results correctly, adhering to expiration dates and appropriate storage requirements, and performing test system function checks or calibration checks). The trainer demonstrates the steps for performing the test. Additional considerations for good testing practices are: Abide by expiration dates and discard expired reagents and test kits as soon as the expiration date elapses. Two types of controls typically found in waived tests are: Internal, procedural, or built-in controls --- evaluate whether certain aspects of the test system are working properly. Personnel and Training Under CLIA, no education or training is required for the director or testing personnel in CW sites. Patient identification --- Identify the patient before collecting the specimen. Questions to address include the following: Management responsibility for testing. The nature of medical procedures and testing in these settings requires expansion of Universal Precautions to include feces, nasal secretions, saliva, sputum, sweat, tears, urine, and vomitus, even when no visible blood is evident. Personnel should be trained and competent in each test they will perform before reporting patient results (32,33). These procedures should be derived from the manufacturer's instructions and should be in a language understandable to testing personnel. Test Reports After the completion of the test, results are documented and reported. Available at . Advances in technology have made tests simpler, contributing to this shift in testing. Posting telephone numbers for manufacturers' technical assistance representatives. These issues are probably caused, in part, by high personnel turnover rates, lack of understanding about good laboratory practices, and inadequate training. In addition, erroneous results from diagnostic tests, such as those for human immunodeficiency virus (HIV) antibody, can have unintended consequences. Prepared by Devery Howerton, PhD, Nancy Anderson, MMSc, Diane Bosse, MS, Sharon Granade, Glennis Westbrook Division of Public Health Partnerships, National Center for Health Marketing, Coordinating Center for Health Information and Service The material in this report originated in the Coordinating Center for Health Information and Service, Steven L. Qualitative --- Tests that detect whether a particular substance, condition, or microbiological organism is present or absent. Atlanta, GA: US Department of Health and Human Services CDC; 2003. The survey findings indicated that 485 (12%) of the 4,214 CW sites surveyed did not have the current manufacturers' instructions available, and 701 (21%) of the 3,317 sites surveyed during 2003--2004 did not check to be sure there had been no changes to the instructions. Voluntary early childhood checks should be expanded to make sure that children's social and emotional development is assessed before they enter pre-school (action 5.2). Procedures and devices for the collection of diagnostic capillary blood specimens; approved standard, 5th ed. The CW sites surveyed estimated performing a broad range of annual test volumes (Figure 2). At present, young Australians at risk of mental ill-health and their families often face many difficulties accessing the support they need. If additional assistance is required, contact the appropriate CMS regional office (. Sundwall, MD, Utah State Health Department, Salt Lake City, Utah. Table 8Return to top. When writing procedures for each CW site, it might be helpful to: Use a template with standard component headings to facilitate writing a new procedure and promote ease of use when performing testing; List all materials needed and how to prepare them before testing; Include instructions for patient preparation and specimen collection; Highlight key steps in the procedure (e.g., test incubation time); List test limitations; Describe actions to take when the test does not perform as expected; Integrate control procedures with the steps for performing patient testing to assure control testing is performed; Include established reference intervals and critical values for the test; and Describe how to record and report results and how to handle critical values. Keenan, MD, Department Family Medicine and Community Health, University of Minnesota, Minneapolis; Michael Laposata, MD, Massachusetts General Hospital, Boston; Margaret Mary McGovern, MD, Molecular Genetics Laboratory, Mount Sinai School of Medicine, Mount Sinai Medical Center, New York, New York; Dina R. COLA. Some tests have not been evaluated for use in specific age groups (e.g., pediatric populations). This report summarizes study findings and provides recommendations developed by the Clinical Laboratory Improvement Advisory Committee for conducting quality waived testing. Clinical Laboratory Improvement Advisory Committee Chair: SUNDWALL, David N. The Occupational Safety and Health Administration (OSHA) and individual state standards require employers to provide a safe and healthy work environment for employees. state agency the state health agency or other appropriate state or local agency that has an agreement under Section 1864 of the Social Security Act and is used by CMS to perform surveys and inspections test system the instructions and all of the instrumentation, reagents, and supplies needed to perform a test and generate results total testing process series of activities or path of workflow for performing testing that can be divided into three major phases; before testing, during testing, and after testing unitized test device a self-contained test device to which a specimen is added directly and in which all steps of the testing process occur. Training and competence assessment; approved guideline-second edition. This included 897 sites in 2002, 1,575 sites in 2003, and 1,742 sites in 2004. Available at . For example, a single product insert might include instructions for performing a waived test using unprocessed whole blood and for performing the same test using plasma, which would not be waived. When CLIA was implemented in 1992, CLIAC was chartered to provide scientific and technical advice and guidance to the U.S. Department of Health and Human Services (HHS) about laboratory standards and their impact on medical and laboratory practice. CDC and the Clinical and Laboratory Standards Institute (CLSI) (formerly NCCLS) have also published information about biosafety and precautions for preventing transmission of bloodborne pathogens in the workplace (26--30). For waived tests in which the specimen is applied directly to the test device (e.g., throat swabs for group A streptococcal antigen), the test strip, cassette, or other device should be labeled with the patient identification before collecting the specimen, especially if more than one test is being performed at the same time. The concerns noted by states were similar to those identified in the CMS pilot studies. State regulations or other governmental agencies might require CW sites to retain documents and records for a specific length of time. Five years after this seminal report, small but consequential changes have occurred that have shifted the focus to improving systems, engaging stakeholders, and motivating health-care providers to adopt new safe practices (8). --- Evaluate staff for color-blindness because this can limit their ability to interpret test results based on color endpoints. Follow the instructions in the most current manufacturer's product insert, without modification, when performing the test. A procedure manual can also include examples of forms used (e.g., charts to record daily test kit storage temperatures, infectious disease reporting forms, or logs for recording control testing and test results) and check lists for personnel training. Becich MJ. Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. 263a PL100-578 (1988). Safety never takes a holiday. Results from these assessment activities should be documented and evaluated, noting any irregularities and the actions taken to resolve problems or improve processes or procedures. Available at . The management staff should demonstrate a commitment to the quality of testing service by complying with applicable regulatory requirements and promoting good laboratory practices. Recommended Practices After Testing After-testing activities include issuing test reports, supplemental or confirmatory testing, public health disease reporting (if required), testing area cleanup, biohazard waste disposal, and documentation of testing activities. Increasingly, these decisions are based on simple tests performed at the point-of-care using devices that are waived from most federal oversight requirements (and are thus designated as waived tests), including requirements for personnel qualifications and training, quality control (QC) (unless specified as required in the test system instructions), proficiency testing (PT), and routine quality assessment. They were developed on the basis of recommendations and other resources that provided additional information for promoting patient safety and the quality of CLIAC waived testing in laboratories or nontraditional testing sites (18--22). Lighting --- Inadequate lighting can negatively affect specimen collection, test performance, and interpretation of test results. Discussion The findings from the CMS surveys and LMSMN studies indicated that the majority of CW testing sites performed testing correctly and provided reliable service. Safety. Overall, the sites represent a nationwide sample and the distribution of CW facility types is similar to the distribution of CW facility types in the United States (Table 2). Other sources for training on waived testing or specific tests include: Manufacturers and distributors who often provide technical assistance, product updates or notifications, and limited training. Washington, DC: National Academy Press; 2000. When procedures are no longer used, they should be removed from the manual and retained with a notation of the dates during which they were in service. The manual should be updated as tests or other aspects of the testing service change and should be reviewed by the director whenever changes are made. Tools for training continue to evolve and are not limited to traditional methods. Arch Pathol Lab Med 2000;124:1122--7. Pay attention to timing for waived tests, particularly unitized test devices that must be read during specific time intervals. Fingerstick and venipuncture collection devices are for one-time use only. Data identifying who provided training were not submitted for all sites in the surveys. Table 6Return to top. State and local regulations. Sometimes, tests can be performed using both processed and unprocessed specimen types, but are waived only for the unprocessed specimens, in which case the product insert should identify the appropriate specimen for the waived test. Preparing the Testing Area, Test Materials, and Equipment Preparing the testing area and materials (e.g., kits, reagents, control materials, and equipment) before testing patient specimens is essential to maintaining efficient workflow and good quality testing (Table 9). New York State's experience with assessment of waived testing and PPMP practices: are we ready for waived HIV antibody tests? The manufacturer's test system instructions and instrument operating manuals should be the primary resource for information and training in CW sites. Waived tests are approved for use only with direct, unprocessed specimens that do not require operator manipulation (Table 8). Wayne, PA: NCCLS; 2002. These medical records and other individually identifiable health information must be protected, whether on paper, in computers, or communicated orally. Date last reviewed: 10/26/2005 Schwartz, MD, Department of Pathology and Laboratory Medicine, Presbyterian Healthcare, Charlotte, North Carolina; Albert H. However, lapses in quality were identified at certain sites, some of which could result in patient harm. Five years after To Err is Human. A comprehensive procedure manual is a valuable resource for CW sites. Training checklists are helpful to ensure the training process is comprehensive and documented. LMSMN obtained additional waived testing data from 1999--2003. Aspects of testing for which records or documentation are recommended include: Test orders Test procedures or work instructions (e.g., written procedures specific to the CW site and current product inserts) Records of testing materials used, test system and equipment function checks, and maintenance --- Daily records of temperatures for refrigerators, freezers, and the testing area, as needed for the tests performed --- Lot numbers, dates used, and expiration dates of test systems and reagents --- Date and time (if applicable) of equipment function checks and any maintenance performed --- As applicable, notifications from manufacturers about product recalls or other problems, especially if the recalls or warnings refer to specific lot numbers or test systems Test results, including any confirmatory or supplemental testing QC testing results and corrective action taken if control results are unacceptable --- Date and time (if applicable) of control testing --- Lot number and expiration date of external controls Records of any test system failures, troubleshooting, and corrective action taken when problems are identified, including related communication with testing personnel Personnel training and competency assessment Records of PT or other external quality assessment Quality Assessment Good laboratory practices can be expanded to include assessment activities to evaluate and improve the quality of CW site testing. Many tests can now be performed using compact or hand held devices by personnel with limited experience and training. Data from CDC and CMS surveys demonstrate that waived testing sites are subject to a high rate of personnel turnover. Before beginning the test, read and understand the test instructions specified in the product insert and included in the CW site's procedures. The form must be signed by the facility owner or the facility director. How will the care offered in the site benefit by introduction of testing or the addition of a new test, and what will it cost? Available at . Voluntary external inspections evaluate the testing site practices and documentation systems, and a more narrowly focused assessment of test performance can be accomplished by participating in performance evaluation programs or subscribing to PT programs. The CLIA program is administered by CMS and is implemented through three federal agencies---CDC, CMS, and the Food and Drug Administration (FDA). For example, when testing for a certain condition or disease in a low-prevalence population, the predictive value of a positive result will be low compared with the predictive value of a negative result. QC testing is designed to detect problems that might arise because of operator error, reagent or test kit deterioration, instrument malfunction, or improper environmental conditions. Institutions should arrange for international students to have health insurance that covers any required mental health treatment (action 6.2). CDC. If results are not recorded directly in a patient's chart, they should be recorded in a written report format that includes all information needed to correctly identify and interpret the results as determined by the testing site (Table 10). Required supplemental/confirmatory testing. Available at . Why is the laboratory an afterthought for managed care organizations? To determine if patients followed the instructions, ask them to explain how they prepared for the test. Lab Tests Online. Gutman, MD, Office of In Vitro Diagnostic Device Evaluation & Safety, Food and Drug Administration, Washington, DC; Thomas L. If repeat testing does not resolve the problem, contact the manufacturer or product technical representative. These requirements might be more or less stringent than federal requirements. In its evaluations, the workgroup considered existing practice guidelines from professional organizations, waived testing recommendations from CMS, personal and professional experience, and publications related to waived testing. **Questions or messages regarding errors in formatting should be addressed to mmwrq@cdc.gov. Laboratory. Testing facilities should confer with local public health agencies for the most current information on required reporting procedures since diseases identified for reporting can change over time, and state requirements might vary. Table 11Return to top. Robinson-Dunn, PhD, William Beaumont Hospital, Royal Oak, Michigan; Lou F. Considerations Before Introducing Waived Testing or Offering a New Waived Test Forethought, planning, and preparation are critical to initiating high-quality waived testing in any type of setting. Survey Findings Demographics CMS surveyed 4,214 CW sites during April 15, 2002--November 12, 2004. Terms and Abbreviations Used in This Report accuracy true or target value; freedom from error; the accuracy of results can be measured by comparing them

to results accepted as correct (e.g., standard methods), or by comparing them with those from another laboratory that uses a comparable method analyte a substance or constituent for which a laboratory conducts testing antibody a protein formed in the body in response to a foreign substance (e.g., bacteria, viruses or chemical toxins) and that interacts with the foreign substance to weaken or neutralize it antigen any substance that, when introduced into the body, causes the development of an immune response, such as antibody production ASN Arkansas Sentinel Network biohazard a biological agent that has the capacity to produce deleterious effects on humans, such as microorganisms and toxins biohazardous waste waste containing pathogens with sufficient virulence and quantity so that exposure to the waste by a susceptible host could result in an infectious disease biosafety the application of combinations of laboratory practice and procedure, laboratory facilities, and safety equipment when working with potentially infectious microorganisms to prevent infection bloodborne pathogens microorganisms that, when present in human blood, can cause disease in humans. This information would then be available to provide guidance to physicians, nurses, and other health-care providers in CW facilities. Proper documentation is necessary for monitoring and assessing test performance, identifying and resolving problems that could affect patient testing, retrieving and verifying information, and maintaining adequate patient and personnel records. Important activities during this phase include QC testing, test performance, result interpretation and recording. Quality control of test systems waived by the clinical laboratory improvement amendments of 1988: perceptions and practices. Labeling procedures should meet the needs of the testing site and should be adequate to prevent specimen mix-up. Certain sites offering waived testing can be certified as part of a larger health-care organization that holds a CLIA Certificate of Compliance or Certificate of Accreditation. Types of controls. Errors can occur anywhere in the testing process, particularly when the manufacturer's instructions are not followed and when testing personnel are not familiar with all aspects of the test system and how testing is integrated into the facility's workflow. Each site should define the critical values, if appropriate, for the tests in use and ensure that testing personnel are aware of these values and the procedure for alerting the clinician. Frequency of control testing. Persons using assistive technology might not be able to fully access information in this file. The specific test system name should be on the quick reference instructions to avoid confusion. Personnel issues to consider include: Is staffing adequate? Co-Chair: Kathryn M. The Productivity Commission’s Mental Health Inquiry presents a long-term plan for a person-centred mental health system that prioritises prevention and early intervention. Although surveyors attempted to include a wide variety of CW sites in the sample, the sites were self-selected by surveyors and selection was based, to some degree, on convenience to the surveyors and willingness of the sites to participate in the voluntary surveys. Eight tests were included in the 1992 CLIA regulations (a ninth test was subsequently added) as meeting these criteria and later, the FDA Modernization Act of 1997 clarified that tests cleared by FDA for home use are automatically waived. Ideally, the person signing the CW application (CMS Form 116) is responsible for management of the testing operations. Practice patterns of testing waived under the clinical laboratory improvement amendments. Regulatory requirements for all OSHA standards, including specific information for medical and dental offices (24), are available at and by telephone, 800-321-6742. Test performance can be assessed, if specimens are suitable, by exchanging specimens with another testing facility using the same test method(s) and comparing the results. Pretest information --- Discuss factors, test limitations, or medical indications that can affect test results with the patient, as appropriate, and provide pertinent information such as pamphlets supplied by the test manufacturer, when specified in the product insert. The predictive value for certain types of test results in a specific patient population depends on the test's sensitivity, specificity, and the prevalence of the condition in the population. What are the physical and environmental requirements for testing? Developing Procedures and Training Personnel After the decision is made to offer waived testing, it is good practice to develop written policies and procedures so that responsibilities and testing instructions are clearly described for the testing personnel and facility director. Atlanta, GA: CDC; 1999. Benefit and Cost Considerations Evaluating the benefits of a particular test. Documents and records. These factors include: Test kits or instruments, supplies not provided with the test, control and calibration materials, inventory requirements for anticipated test volume (including seasonal testing), and the shelf life of test components and supplies. By following these recommendations, errors that could potentially lead to patient harm and the associated morbidity and mortality can be prevented. Of the CW facility types surveyed, POLs compose the largest percentage (47%), followed by skilled nursing facilities (14%) (Table 2). By implementing these recommendations, CW sites could improve quality, reduce testing errors, and enhance patient safety. What federal, state, and local regulations apply to testing, and is the site adequately prepared to comply with all regulations? Table 5Return to top. Specimens and, in some cases, test devices need to be appropriately labeled to prevent mix-up. Davidson, MBA, West Georgia Health System, LaGrange, Georgia; Kathryn M. The trainer evaluates test performance, provides feedback and additional instruction, and follow-up evaluations to ensure effective training. Of the CW facilities CMS surveyed, 12% did not have the most recent instructions for the waived test systems they were using, and 21% of the sites reported they did not routinely check the product insert or instructions for changes to the information (Table 5). The National School Reform Agreement, which sets out governments’ expectations for the education system, funding structures, and reporting requirements, should be updated to include student wellbeing as one of its outcomes. Stahmer, Golden, Colorado; Lou F. This information might be incorporated into the facility's procedures or posted for quick reference. Although product inserts can be used as test procedures, these instructions will typically need to be supplemented with testing information that is unique to the CW site's operations and workflow (31). Patient Safety Concerns Related to Waived Testing Efforts to reduce medical errors, improve health-care quality, and increase patient safety have been gaining national attention. Mody, MD, The Methodist Hospital, Houston, Texas; Valerie L. Type 508 Accommodation and the title of the report in the subject line of e-mail. M29-A3). Verbal reports of test results should be documented and followed by a written report. Information management: moving from test results to clinical information. Who will be responsible and accountable for testing oversight at the CW site, and does this person have the appropriate training for making decisions on testing? Centers for Medicare and Medicaid Services. These pilot surveys identified quality issues that could result in medical errors (10). Leape LL, Berwick DM. Personnel Training Trained and competent testing personnel are essential to good quality testing and patient care. For example, results from waived tests can be used to adjust medication dosages, such as prothrombin time testing in patients undergoing anticoagulant therapy and glucose monitoring in diabetics. Crenshaw, MD, Stone Mountain, Georgia; Jacinto Del Mazo, MD, Del Mazo Medical Services, Atlanta, Georgia; Paula W. On-the-job training should include the following steps: The trainee reads the testing instructions. Second, the CMS data were collected and entered into the database by a large number of persons, introducing variability. If there is a question, check with the ordering clinician. Transmission of hepatitis B virus among persons undergoing blood glucose monitoring in long-term-care facilities---Mississippi, North Carolina, and Los Angeles County, California, 2003--2004. Recommended Practices Before Testing Preparations before performing patient testing are a critical element in producing quality results. An estimated 7--10 billion laboratory tests are performed each year in the United States (1,2), and laboratory test results influence approximately 70% of medical decisions (2--4). At a minimum, external controls should be tested with each new shipment of utilized test devices, when testing a new lot number, and by each new operator before conducting testing. Available . Resource needs to manage public health reporting, if required nationally or by the state. In addition, certain public health testing sites offering only waived testing can be included under a limited public health or mobile testing exception. H04-A3-V) 1994. Under HIPAA, CW sites are required to establish policies and procedures to protect the confidentiality of health information about their patients, including patient identification, test results, and all records of testing. Waived testing data were collected by CMS to provide an assessment of testing practices, promote good laboratory practices, and encourage improvement through educational outreach. Records or logs of test results should have enough detail so the test site can retrieve information. Insufficient timing can result in false negative or invalid results because the specimen might not react completely with test system reagents. What written documentation will be needed, and how will test records be maintained? The person responsible for testing oversight and decision-making should review records periodically. Schwartz, MD, Department of Pathology and Laboratory Medicine, Presbyterian Healthcare, Charlotte, North Carolina. CLIAC also includes three ex officio members from CDC, CMS, and FDA. CDC. Both trainer and trainee document completion of training. NCCLS. Procedures should be in place to ensure documentation of critical values and timely notification of the proper medical personnel. --- Take into account the staff turnover rate and the ongoing need to provide training for new personnel. Surveyors self-selected CW sites on the basis of test volume, location, and facility types. Patient population --- Consider the population that will be tested before offering a test. Figure 3Return to top. Because names can be similar and lead to confusion, use birth dates, middle initials, identification numbers, or other means to ensure the specimen is collected from the correct patient. Designating an appropriately trained person, who understands the responsibilities and impact of changing from one test system to another, to discuss new products with sales representatives. Test controls at the frequency determined by the CW site. The Arkansas Sentinel Network (ASN) consisted of 94 local health units integrated into the state health agency (mostly waived testing sites) and approximately 600 waived and nonwaived laboratories in Arkansas and surrounding states. Universal Precautions is one component of Standard Precautions, a broader approach designed to reduce the risk for transmission of microorganisms from both recognized and unrecognized sources of infection in hospitals; Use of safer, engineered needles and sharps; Use of personal protective equipment (PPE) such as gloves and protective eyewear; Provision of hepatitis B vaccination at no cost for those with possible occupational exposure who want to be vaccinated; Safety training for handling blood, exposure to bloodborne pathogens, and other infectious materials; and Equipment for the safe handling and disposal of biohazardous waste (e.g., properly labeled or color-coded sharps containers and biohazard trash bags and bins). Robinson-Dunn, PhD, William Beaumont Hospital, Royal Oak, Michigan; Jared N. Figure 2Return to top. Although data have not been systematically collected on patient outcomes with waived testing, adverse events can occur (9). NYSN reported that registered nurses (RNs) and licensed practical nurses (LPNs) served as testing personnel in 84% of the limited service laboratories they surveyed (13). Although the surveys were conducted through several mechanisms, the findings lead to similar conclusions about lapses in quality in CW sites, and they highlight the need for additional education and training related to waived testing for CW site directors and testing personnel. Baltimore, MD: Centers for Medicare and Medicaid Services. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, hepatitis B virus, hepatitis C virus, and other bloodborne pathogens. Most testing is not waived and is typically performed in hospital or reference laboratories (Certificate of Compliance and Certificate of Accreditation), which comprise 20% of the total number of testing sites (Figure 1). The Health Insurance Portability and Accountability Act of 1996 (HIPAA) established federal privacy standards to protect patients' medical records and other health information provided to health plans, doctors, hospitals, and other health-care providers. Tests can be waived under CLIA if they are determined to be "simple tests with an insignificant risk of an erroneous result" (5). Selecting, evaluating, and using sharps disposal containers. The CW site should have written policies to ensure confirmatory and supplemental testing is performed when needed. This workgroup was comprised of key stakeholders in waived testing (i.e., CLIAC members; physicians; nurses; laboratorians; manufacturers; distributors; and representatives from CDC, CMS, and FDA). These instructions, as outlined in the product insert, include directions for specimen collection and handling, control procedures, test and reagent preparation, and instructions for test performance, interpretation, and reporting (Table 7). Test results are of the following two types: Quantitative --- Tests that provide numerical results generated by the test device or instrument. During 1999--2001, CMS conducted on-site surveys of a representative sample of CW sites in 10 states to assess the quality of testing in these sites. Specific information on the Bloodborne Pathogens Standard and needlestick prevention is available at . Blood glucose testing in settings without laboratory support; approved guideline. Clin Leadersh Manag Rev 2000;14:296--300. Sometimes a test that can be performed using different specimens or procedures might be waived only for certain specimen types or procedures. The volume of Medicare Part B reimbursed waived laboratory testing in 2004 represented 8% of the total reimbursed testing volume for that year, a 57% increase over the volume in 2000 (Table 1). Directions for specimen collection, handling, and storage are included in the product insert and must be followed explicitly. Do not use product inserts that are out of date for the test system currently in use. Waived tests include test systems cleared by FDA for home use, and simple, low-risk tests categorized as waived under CLIA. Extreme temperatures can degrade reagents and test components, impact reaction times, cause premature expiration of test kits, and affect the test results. NYSN observed similar findings but noted increased compliance with state requirements for documentation/recordkeeping when laboratories had formal affiliations with New York State-licensed laboratories (11). Some waived tests have potential for serious health impacts if performed incorrectly. Since the 1992 inception of the program implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA), the numbers of waived tests and the sites that perform them have increased dramatically. Foucar, MD, Department of Pathology, University of New Mexico, Albuquerque, New Mexico. States and local jurisdictions vary as to the extent to which they regulate laboratory testing. Invalid results might indicate a problem with the specimen or the test system. Instructional videos, workshops, computer-based programs, and other methods can be used. When a CW site collects specimens for referral, procedures should include the following: Instructions for ordering additional tests, contact information for the referral laboratory used, and examples of completed test request forms. For each waived test that requires additional testing, the CW site should document the processes and procedures necessary to manage referral or confirmatory testing. Recordkeeping and information systems. The data demonstrate a need for educational information among CW site directors and testing personnel about the importance of following manufacturers' instructions, adhering to expiration dates, performing QC testing, and proper documentation and recordkeeping. An original paper copy of this issue can be obtained from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, DC 20402-9371; telephone: (202) 512-1800. Laboratory testing affects persons in every life stage, and almost everyone will experience having one or more laboratory tests conducted during their lifetime. Surveys of Waived Testing Sites Methods During 2002--2004, approximately 150 CMS and state agency surveyors conducted on-site surveys nationwide using a questionnaire at 4,214 sites performing testing under a CLIA CW. Numerical results are values corresponding to the concentration of the specific substance being measured. These test results might require additional testing before a definitive test result is obtained, and patients might need posttest counseling about the meaning of the test result. To help both parents and their children, governments should improve screening for mental ill-health among new parents, including improving the collection of data and monitoring of screening rates (action 5.1). This conversion may have resulted in character translation or format errors in the HTML version. Test Results Interpretation When the test is complete, interpret the results according to instructions in the product insert (including the quick reference guide). In the past, tests such as prothrombin time, cholesterol, and glucose either used complex manual methodologies or were performed using sizable instrumentation suitable for use by highly trained personnel in traditional clinical laboratory settings. Institutional support for tertiary students with mental ill-health needs improvement: Tertiary education institutions should be required to have a student mental health and wellbeing strategy — including staff training — as a condition for their registration (action 6.3). Depending on workflow, specimen labeling also might include the date and time of collection and identification of the collector. Findings from a PNWSN study indicated that the highest percentage of personnel were initially trained by another employee (25%) or trained themselves by using instructions provided with the waived test system (17%) (15). Patient reports should be legible and reported in a timely manner to the appropriate person. A calibration check is a mechanism to be sure the test system has remained stable and the results remain accurate centrifugation a process of separating blood or other body fluid cells from liquid components using a device (centrifuge) containing compartments that spin rapidly around a central axis CLIA Clinical Laboratory Improvement Amendments of 1988 CLIAC Clinical Laboratory Improvement Advisory Committee CLSI Clinical and Laboratory Standards Institute (formerly NCCLS) CMS Centers for Medicare & Medicaid Services competency assessment evaluation of a person’s ability to perform a test and to use a testing device; this includes all aspects of testing, from specimen collection to result reporting confirmatory test an additional more specific test performed to rule out or confirm a preliminary test result to provide a final result control a device or solution used to monitor a test system to ensure proper test performance and correct results critical values test results that require immediate notification to the clinician for patient evaluation or treatment CW Certificate of Waiver CW testing site the location where waived testing takes place; a facility holding a CW diagnostic test a test that identifies a disease or condition direct microscopic examination the direct examination of a patient specimen using a microscope external controls control materials that mimic patient specimens and monitor the testing process from specimen application to result interpretation FDA Food and Drug Administration FDAMA FDA Modernization Act HHS United States Department of Health and Human Services HIPAA Health Insurance Portability and Accountability Act of 1996 HIV human immunodeficiency virus internal controls procedural or built-in controls; controls that are built into a testing device and designed to verify that the test system is working as expected kit a packaged set containing test devices, instructions, reagents, and supplies needed to perform a test and generate results LMSMN Laboratory Medicine Sentinel Monitoring Network nonreactive or NR a result that indicates the absence of the constituent that the test is designed to detect nonwaived tests complex tests that do not meet the CLIA criteria for waiver and require training and specific quality measures to ensure the accuracy and reliability of test results NYSN New York Sentinel Network OIG Department of Health and Human Services Office of Inspector General OSHA Occupational Safety and Health Administration plasma the liquid portion of anticoagulated blood that does not contain cells. Six percent of CW sites did not perform follow-up confirmatory tests as specified in the instructions for certain waived tests (e.g., group A streptococcal antigen), and 5% did not perform function checks or calibration checks to ensure the test system was operating correctly. Joint Commission for International Patient Safety. These pathogens include, but are not limited to, hepatitis B virus, hepatitis C virus, and human immunodeficiency virus (HIV) calibration (check) the process of testing and adjusting an instrument or test system to provide a known relationship between the value of the substance being measured by the test and the test system’s measurement response. Flu activity. Meeting these environmental conditions can be challenging in nontraditional settings (e.g., health fairs) or community outreach venues (e.g., shopping malls, meeting rooms, parks, parking lots, mobile vans, and buses). Containers and collection devices might have additives that affect the specimen or are part of the test and should not be substituted or altered. Specific state agencies and contacts are available at . To apply for a CLIA certificate, CMS Form 116 (must be completed and sent to the state agency for the state in which the testing site is located. Although the testing performed in CW sites accounts for 65 years and certain disabled persons, covers diagnostic laboratory testing. Additional Measures to Help Testing Staff Ensure Reliable Results The CW site director or person overseeing testing should promote quality testing and encourage staff to ask questions and seek help when they have concerns. Recording Results Record test results according to the site's policy. Comments from this study reflected the thinking that training is not always necessary or that minimal time should be spent on training because persons have been trained in school or on other jobs. Certain test systems might have electronic internal controls to monitor electronic functions. Documentation. Available at . Maintaining records of referred testing is important for patient care and follow-up. Committee on Quality of Health Care in America, Institute of Medicine. Continued monitoring of waived testing, with a focus on personnel education and training, is needed to improve practices and enhance patient safety as waived testing continues to increase. Permit announced or unannounced on-site inspections by CMS representatives. Background CLIA Requirements for Waived Testing All facilities in the United States that perform laboratory testing on human specimens for health assessment or the diagnosis, prevention, or treatment of disease are regulated under CLIA (5). Universal Precautions an approach to controlling infection. Approximately 1,600 test systems representing at least 76 analytes are waived under CLIA (Table 1). Clarke LM, Jenny R, Shulman S, Reilly A, Olsen C. Specific considerations include: Intended use -- Be aware of the intended medical use for which FDA approved the test system as explained in the product insert. How reliable is laboratory testing? This includes a number of recommended actions to improve the social and emotional wellbeing of children and young people. schools being required to report on their progress against wellbeing outcomes, with school principals being accountable for these outcomes. Work space --- Work surfaces should be stable and level and be able to be adequately disinfected; work space should be adequate in size for patient confidentiality, ease of specimen collection, test performance, and storage of supplies and records. As described in the IOM report, errors most often occur when multiple contributing factors converge, and preventing errors and improving patient safety require a systems approach. Baltimore, MD: Centers for Medicare and Medicaid Services; 2001. Chapin, MD, Department of Pathology, Rhode Island Hospital, Providence, Rhode Island; Mary Beth Clark, Emory Healthcare, Atlanta, Georgia; Martha H. The findings in the 2002--2004 CMS surveys are subject to at least three limitations, and caution should be used in extrapolating the survey data to make generalizations about waived testing. The CMS surveys indicated that 5% of CW sites were conducting tests that were not waived, the most frequently performed nonwaived procedures (72%) being direct microscopic examinations (e.g., potassium hydroxide preparations, wet mounts, or urine sediment examinations). Point-of-care in vitro diagnostic (IVD) testing; approved guideline; AST2-A, Wayne, PA: NCCLS 1999. The training process. The quality issues identified through these surveys might have been caused, in part, by high turnover rates of testing personnel in CW sites, inadequate training with respect to waived testing, and lack of understanding of good laboratory practices, including the importance of following all aspects of the manufacturers' instructions. In addition, control records should be kept in the order in which they were completed so they can easily be compared with test records if there are questions about testing performed within a specific time period. They can be disseminated by a variety of individuals and organizations and adapted for use in different settings where waived testing is conducted. Pretest instructions --- Some tests require special preparation on the patient's part (e.g., a fasting state for glucose testing). Clin Leadersh Manag Rev 2004;18:65--9. H04-A5) 2004. Need for supplemental testing or patient follow up --- Some waived tests provide preliminary results as part of a multitest series (e.g., rapid HIV testing) or results that must be considered in conjunction with other medical information. In response, the committee recommended publication of the 2002--2004 CMS data in conjunction with other data pertinent to waived testing performance along with recommendations for good laboratory practices for waived testing sites. Because the list of waived tests is constantly being revised as new test systems are added, the most current information about waived tests and appropriate specimens is available at . Although not usually specified in the product insert (and therefore not a CLIA requirement), proper documentation and recordkeeping of patient and testing information are also important elements of good laboratory practices. Test procedures should describe the type of controls to be used, how to perform QC testing (including QC testing frequency), and actions to be taken when QC results are unacceptable. Training should be provided by a qualified person (e.g., experienced co-worker, facility expert, or outside consultant) with knowledge of the test performance, good laboratory practices, and the ability to evaluate the efficacy of the training. How will introduction of testing affect the current work flow, are there sufficient personnel to conduct testing, and how will they be trained and maintain testing competency? Hearn, MD, National Center for Health Marketing, CDC, Atlanta, Georgia; Judith Yost, MA, Division Laboratories Services, Center for Medicaid and State Operations, Centers for Medicare & Medicaid Services. These programs provide challenge samples to test as if they were patient specimens and the results are evaluated with respect to how close they are to the intended target values. Hui, MD, Northwest Arkansas Pathology Associates, Fayetteville, Arkansas; Kevin P. Available at . References Steindel SJ, Rauch WJ, Simon MK, Handsfield J. In addition, measures such as QC, PT, adequate documentation, and monitoring are required to ensure the accuracy and reliability of nonwaived test results. Albany, NY: New York State Department of Health Wadsworth Center. What are the safety considerations for persons conducting testing and those being tested? Cost considerations. Within LMSMN, the Washington State Department of Health established the Pacific Northwest Sentinel Network (PNWSN), which included approximately 650 waived and nonwaived laboratories in Alaska, Idaho, Oregon, and Washington. This section describes what is being measured by the test, the type of specimen for which it is approved, and whether it is a quantitative or qualitative measurement. This correlates with data for the top five waived tests identified through the LMSMN, especially for POLs (11).

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