CLIAC Waiver Recommendations as of November 5, 2014
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DATE RECOMMENDED	MEETING BACKGROUND	CLIAC RECOMMENDATION	STATUS
Oct. 28-29, 1992	• Concern expressed over waived testing and the addition of waived tests to the list in the regulations. Others saw the need for waived testing so as not to deny access to care. Potential waiver of the Hemocue hemoglobin test was specifically discussed, especially as compared to other tests waived by regulations. • A member suggested that since FDA uses a determination of equivalency for clearing products for marketing, determining equivalency to an already waived test may be a process for determining whether tests could be waived.	Add hemoglobin testing by the Hemocue instrument to the list of waived tests and recommend reviewing the list of waived tests for the appropriate application of the waiver criteria.	Added "hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout" to the waived test list in regulations published in the *Federal Register* on Jan. 19, 1993.
Feb. 17-18, 1993	The CLIAC summary reflects public comments and limited discussion on test categorization and waiver, but does not include background on the recommendations listed at the close of the meeting.	Develop definitive criteria for determining waived status of tests. Declare a moratorium on further review of tests for waived status until the definitive criteria are developed.	CDC declared a moratorium on waiver determinations following the CLIAC meeting. The moratorium was lifted in December 1994 when draft guidelines containing clarified waiver criteria and process for reviewing waiver requests was issued to manufacturers of moderate complexity test systems.
Feb. 17-18, 1993	Following a report from CLIAC Test Categorization Subcommittee, the Committee discussed the pros and cons of whether rapid strep tests should be considered for waived status, as raised by the Subcommittee.	Do not add rapid strep test to the list of waived tests listed in the regulations.	After the moratorium was lifted and criteria for waiver were clarified, a number of rapid strep tests have met the CLIA requirements for waiver and are categorized as waived.
May 26-27, 1993	Although the waiver moratorium was in place, since a representative from Chemtrak had requested waiver of the Single Analyte Cholesterol Accumeter at CLIAC meetings prior to implementation of the moratorium, the Chair agreed to consider this instrument for waiver at the meeting.	Waive Chemtrak Single Analyte Cholesterol Accumeter.	Chemtrak Cholesterol Accumeter waived; manufacturer notified March 17, 1995, included in the test categorization notice published in the *Federal Register* on July 8, 1996.

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Aug. 12, 1993	At the CLIAC meeting on August 12, 1993, CDC presented proposal for applying criteria for waiver: • Qualitative tests -Must meet standards for: o Operational characteristics o Ease of use criteria o Performance characteristics including Phase I-Random Error, Phase II- Systematic Error, Phase III-Constant and Proportional Error, and departmental review. • Quantitative tests - Must meet standards for: o Operational characteristics o Ease of use following protocol, performance characteristics including Phase I-Random Error, Phase II-Systematic Error, Phase III-Constant and Proportional Error, Total Test Performance, and departmental review.	•Clarify criteria for waiver. •Eliminate 'risk of harm' as a criterion for waiver. •Revise criteria to include "simple laboratory tests and examinations which have an insignificant risk of producing an erroneous laboratory test result." •Re-evaluate tests currently on the waived list.	Clarifications to the criteria for waiver and proposal to reevaluate currently waived tests included in the proposed regulation published in the *Federal Register* on Sept. 13, 1995.
Aug. 12, 1993	• At the CLIAC meeting on May 26-27, 1993, the issue of whether any test cleared for home use by the FDA was automatically waived was referred to the CLIAC Subcommittee on Test Categorization for discussion. • At the CLIAC Subcommittee on Test Categorization meeting on June 22, 1993, the FDA representative's presentation stated that he believed the FDA home use approval process had limitations. The main criteria used by the FDA for these approvals are intended use, data in support of intended use, and risk of harm.	Require that all tests, including any cleared by the FDA for home use, meet the CDC proposed guidelines for waiver.	On November 9, 1997, Congress passed the FDA Modernization Act, which revised the CLIA law to require that any test approved by the FDA for home use be waived under CLIA. As a result, test systems cleared by the FDA for home use are automatically waived.

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Sept. 27-28, 2000	CLIAC raised a number of issues regarding the criteria and process for waiver currently being developed and used by the FDA, after FDA received responsibility for waiver determinations on December 30, 1999. Their concerns centered around: • interpretation of the CLIA and FDAMA statutes regarding waiver • definitions for accuracy, precision, and risk of harm • intended use of waived tests • studies required for waiver determinations • off-label use of waived tests • waiver based on over the counter or prescription home use • post-analytic concerns • post-market surveillance • the absence of required standards for laboratories performing waived testing • potential waiver of new technology	Send a letter to the Secretary, HHS, requesting opportunity to provide comments on waiver process and recommend FDA follow the guidelines for waiver approval published in the September 1995 proposed rule.	CLIAC sent a letter to the HHS Secretary on September 28, 2000, informing her that they had formed a workgroup which would meet to provide input for CLIAC to make recommendations regarding the waiver process. Until that time, CLIAC recommended that FDA follow the guidelines for waiver approval published in the September 1995 proposed rule.
Feb. 7-8, 2001 and May 30-31, 2001	CLIAC made the following suggestions pertaining to the FDA Draft Guidance: • Use the words “accuracy,” “precision,” and “comparability” appropriately. • In the QC section of the Draft Guidance, change the word “should” to “must,” and state, “When QC is required, the following principles apply...” • To document the ability of an untrained user to follow the package insert and perform the test properly, the manufacturer must test the ability of the user to understand quality control and test patient samples. • Waiver studies should include a representative sample of intended users (e.g. nurses) to provide a valid comparison of comparability between trained users and users untrained in laboratory practice. At the May 30-31, 2001, meeting CLIAC discussed the issues considered by the Waiver Workgroup, including	Provide comments to FDA on the Draft Waiver Guidance.	Comments on all aspects of the FDA Draft Waiver Guidance were verbally presented to FDA representatives on February 7-8, 2001 and May 30, 2001. A letter containing CLIAC comments was sent to FDA on June 8, 2001.

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	home use approval, accuracy, comparability studies, risk of harm, appropriate tests for waiver, quality control testing, labeling, surveillance/post-approval monitoring, general comments, and concerns.		
May 30-31, 2001	CLIAC discussed the potential waiver of rapid HIV tests and noted there are elements other than simplicity and accuracy to consider; agreed counseling is critical to the clinical management of HIV; and suggested increasing access to moderate complexity rapid HIV testing through the use of the limited public health certificates, rather than offering them as waived tests.	Develop a statement reflecting concerns about waiver of rapid HIV tests for presentation to FDA at their Blood Products Advisory Committee (BPAC).	The statement representing CLIAC concerns was presented at the FDA BPAC on June 14, 2001.
Jan. 30-31, 2002	Following FDA's withdrawal of the draft waiver guidance due to clarification of the CMS authority to issue CLIA rules and guidances, CLIAC was asked whether to redirect their June 2001 comments to FDA to the Secretary HHS as general recommendations for rule-making pertaining to the waiver review criteria and processes.	Readdress CLIAC's June 8, 2001 letter to FDA (providing the Committee's recommendations relative to FDA's Draft Waiver Guidance) to the Secretary, HHS, as recommendations to be used in rule-making relative to the waiver review criteria and processes.	The recommended letter was sent by CLIAC to the HHS Secretary on January 31, 2002.
Sept. 11-12, 2002	CLIAC continued previous discussions regarding the status of and issues surrounding waiver and rapid HIV tests. Concerns were noted while, at the same time, the need for access to testing was expressed.	Send a letter to the Secretary, HHS, recommending: (1) appropriate oversight, training, QA, QC, and PT are needed for even the simplest HIV testing device, (2) careful review of objective evidence of test performance by testing personnel in waived settings is needed before a rapid HIV device is considered for waiver, and (3) the limited public health certificate exception under CLIA would allow	The recommended letter was sent by CLIAC to the HHS Secretary on September 12, 2002.

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		rapid HIV tests to be used without compromising public health.	
Sept. 17-18, 2003	A history of waiver was presented. This included the review of the 1995 waived testing proposed rule, previous CLIAC recommendations, and a waiver criteria proposal submitted to CMS and FDA by AdvaMed.	Convene a Waiver Workgroup including key stakeholders to review the testing concerns, data on the process of waiver determination and performance of waived tests, and any other relevant information; report to CLIAC the outcome of the Workgroup's deliberations regarding appropriate changes to the waiver determination process and oversight of waived tests.	Workgroup comprised of federal agencies, industry, laboratory professionals, POLs, CLIAC, and other stakeholders met on January 16, 2004, to consider suggestions for changes to the waiver determination process and oversight of waived tests. Waiver Workgroup reported to CLIAC on February 11, 2004.
Feb.11-12, 2004	A report from the Waiver Workgroup included suggestions made pertaining to criteria for demonstrating “simple” and “insignificant risk of an erroneous result” for waived test determinations. The report also addressed waiver studies, labeling of waived test systems, possible sales restrictions, good laboratory practices, and post-waiver reporting/surveillance.	Based on CLIAC Waiver Workgroup Report, the Committee provided recommendations for development of criteria and oversight guidelines for waived testing to FDA and shared these recommendations with AdvaMed.	CLIAC recommendations were sent to FDA and AvaMed on April 8, 2004.

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Feb. 11-12, and Sept. 22-23,2004	In addition to the Waiver Workgroup report containing suggested good laboratory practices for waived testing, CMS provided data and anecdotal information from their Certificate of Waiver pilot project to assess waived testing practices. CMS then presented additional data at the Sept. meeting. CLIAC members were interested in potential publication of the data and Workgroup suggestions and requested followup through a subsequent workgroup and report. A more comprehensive report that also included CDC's Laboratory Medicine Sentinel Monitoring Network (LMSMN) waived testing data was suggested.	Convene a workgroup to investigate the feasibility and process for publishing CMS Certificate of Waiver laboratory survey data in CDC's Morbidity and Mortality Weekly Report (MMWR).	A Workgroup comprised of physicians, nurses, laboratory professionals, manufacturers, distributors, and government representatives met on January 12, 2005, and considered options for publication of CMS' Certificate of Waiver laboratory survey data and waived testing practice guidelines.
Feb. 16-17, 2005	The Good Laboratory Practices for Waived Testing Workgroup report was presented, which included suggestions for considerations before testing, and test performance throughout the total testing process (pre-testing, testing, and post-testing phases). In addition, general comments to be considered in the waived testing publication were provided.	Based on the Workgroup report, CLIAC provided recommendations for good laboratory practices for waived testing, to include considerations before testing, and test performance throughout the total testing process (pre-testing, testing, and post-testing phases).	CLIAC recommendations for good laboratory practices for waived testing, along with CMS and LMSMN waived testing data, were published November 11, 2005, in the *MMWR,* Vol.54, No. RR-13.
Sept. 11-12, 2008	Following Committee discussion on waived testing, especially as related to potential waiver of complete blood counts with differentials, a member commented that there is a lack of data on whether or not waived testing improves the outcome of patients and suggested a study be performed to assess the benefits and risk of waived testing.	Conduct a study to gather data about the impact of waived testing on patient outcomes, clinician behavior, and other similar issues.	HHS is focused on monitoring and quality improvement though CMS 2% educational surveys of waived testing sites, FDA device monitoring, and CDC distribution of guidelines and training materials.
Sept. 2-3, 2009	There were multiple presentations on assessing the impact and performance of waived tests from CDC, CMS and several proficiency testing (PT) programs that offer PT modules for waived testing. CLIAC was asked to consider the gaps in waived testing data, how to better address the gaps and measure the impact and outcomes of waived testing.	CMS should survey each Certificate of Waiver (CW) laboratory to: 1) determine which tests they perform, 2) identify who performs the testing, 3) verify that all testing personnel have been trained and shown to be competent for each test they perform, and 4) verify that laboratory has a	CMS now surveys 2% of waived testing sites every year. Accreditation agencies also survey some waived testing sites. Sufficient resources are not available to allow CMS to survey all Certificate of Waiver testing sites.

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		copy of the manufacturer's current instructions for the test, and that testing personnel follow these instructions when performing testing. A pilot study of a subset of CW laboratories should be conducted prior to extending the survey to all CW laboratories.	