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# CLIA Waiver Assessment of Accuracy and Concepts in Study Design: Overview of a Proposal for Consideration

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# Background

- Ongoing discussion regarding CLIA waiver accuracy study design
- Progress made, but continued discussions with FDA as essential
- Public health need to support access and innovation in point of care testing
- Focus of discussion—appropriate demonstration of whether a test is accurate for purposes for CLIA waiver purposes
- Significant stakeholder support for improving process
- CLIA waiver reform in House 21st Cures; also Senate stand-alone legislation

# Critical Industry/FDA Commitment

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- Apart from legislation, FDA/industry joint commitment to
  - Timely commence this priority discussion and
  - work to revise Section V of CLIA waiver guidance [Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices," issued on January 30, 2008] to include appropriate use of comparable performance between a waiver user and moderately complex laboratory user to demonstrate accuracy
- Appreciate FDA commitment to work with industry; critically important to diagnostics industry

# Status of 2008 CLIA Waiver Guidance

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- Collaboration of AdvaMedDx and CLIA Waiver Coalition *(jointly supported proposal)*
- Proposal would revise Section V of CLIA Waiver Guidance
- Addresses “accurate” for CLIA waiver purposes, and provides different options for evaluating whether a test is “accurate” for CLIA waiver purposes under the Agency’s current interpretation of accuracy
- Caveat—This is an overview of proposal. Detailed discussion planned with FDA.

# Highlights of Proposal

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- This proposal addresses “accurate” in the context of CLIA waivers to mean that the skill of the user does not have a meaningful impact on results obtained under intended operating conditions (i.e., as used in Certificate of Waiver testing facilities at the point-of-care).

- Thus, the purpose is to evaluate the effect that the “user” has on test results, not to revalidate previous determinations with respect to safety and effectiveness.

# Highlights of Proposal

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- The objective  is to assess whether specialized laboratory training and experience of operators found in moderate and high complexity test settings, including those medical personnel who perform tests in moderate or high complexity point of care settings (“Trained Users”) achieve the same results as operators that are expected to be found at Certificate of Waiver sites (“Untrained Users”).

# Highlights of Proposal

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- Untrained Users should be provided with whatever materials they would have access to when purchasing the test. This could include traditional instructions for use ("IFU"), a "start-up" card or "Quick Reference Guide" that explains how to use the test, or visual or audio aids (e.g., instructional videos provided with test kits) if these are included in the materials provided to customers.

# Highlights of Proposal

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- The CLIA waiver studies would collect fresh samples from subjects under real world conditions and presentations. For example, if a test is intended for screening unknown infections or other health conditions in persons with certain clinical presentations, the subjects in the study would reflect those patients.
  - allows the use of fresh, banked, and contrived samples

# Next Steps

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- Appreciate FDA commitment to work with industry
- Look forward to rolling up sleeves and working through issues
- More to come; upcoming discussion planned with FDA

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