



Child and Adolescent Health Centers Program (CAHC) Fiduciary Requirements for Laboratory Set Up Content Relevant to: CAHC and SWP Models

Laboratory set up and function, in compliance with CLIA and any other requirements, is the responsibility of the fiduciary. This checklist includes Planning, Working Lab Preparation, Personnel Training/Competency, and Other Considerations to help organize your process. CAHC and SWP laboratory best practices are also included below to take into consideration in your start up process.

LAB PLANNING	
<input type="checkbox"/>	Determine scope of lab services using target population/community data to inform space requirements for equipment, refrigeration, etc. and the testing procedures to be provided (storage for point-of-care tests, machines, controls) NOTE: At minimum, pregnancy testing and HIV testing (CAHC requirement)
<input type="checkbox"/>	Include lab space essentials when finalizing decisions on where the site space will be located NOTE: Consider space requirements for immunizations and/or other medications. Immunization storage and preparation often share laboratory space (immunization services a CAHC requirement MPR #1)
<input type="checkbox"/>	Include lab space essentials in construction/renovation of new/existing site
<input type="checkbox"/>	Budget for purchasing required equipment, supplies, testing materials, PPE, spill kit, etc.
<input type="checkbox"/>	Apply for appropriate CLIA license or certificate of waiver and/or add to fiduciary existing CLIA certificates
<input type="checkbox"/>	Appoint/designate a “Lab Director”
<p>For more information about CAHC and SWP requirements and best practices regarding LAB PLANNING, refer to:</p> <ul style="list-style-type: none"> • Laboratory Space Configuration and Storage Guidance (in Laboratory Services Toolkit) • CLIA Application - CMS 116 CLIA Application • CLIA Brochure - CMS Lab Director Responsibilities 	

WORKING LAB PREPARATION	
<input type="checkbox"/>	Develop lab policies & procedures (P&P): <ul style="list-style-type: none"> • General lab operation P&Ps • Consents for service (parent and minor)
<input type="checkbox"/>	Assemble a Lab Manual for the site defined as: <ul style="list-style-type: none"> • Point-of-care (POC) test manufacturer package inserts • Safety Data Sheet (SDS) for lab materials • CAHC and/or SWP standing orders specific to lab testing • Laboratory policy and procedure (i.e., send out tests)
<input type="checkbox"/>	Develop lab standing orders as appropriate for the site/model
<input type="checkbox"/>	Establish process for consultation on “out of normal” test results as needed
<input type="checkbox"/>	Develop methods/materials for all required documentation
<input type="checkbox"/>	Determine if/how point-of-care testing will be billed
<input type="checkbox"/>	Determine need for reference lab(s) to send out specimens and/or proficiency testing <ul style="list-style-type: none"> • Contracts or agreements completed/consider confidential billing issues • Reference lab(s) materials/access/transport or pickup
<input type="checkbox"/>	Post CLIA license or certificate of waiver appropriate for testing conducted in lab area
<p>For more information about CAHC and SWP requirements and best practices regarding WORKING LAB PREPARATION, refer to:</p> <ul style="list-style-type: none"> • CAHC Clinical Laboratory Requirements and Best Practice Considerations (in Laboratory Toolkit) • Ready? Set? Test! Booklet Self-Assessment Checklist & Tips and Reminders • MMWR Good Laboratory Practices • Michigan Department of Health and Human Services (MDHHS) Lab Services 	

PERSONNEL TRAINING/COMPETENCY	
<input type="checkbox"/>	Designated staff who will perform any/all lab functions receive training
<input type="checkbox"/>	Designated staff reach “competence” for each test performed on site and annually
<input type="checkbox"/>	Designate an outside laboratory to complete proficiency testing for any moderate complexity test desired (i.e., microscopy, KOH slides)
<input type="checkbox"/>	Designated staff are oriented to CAHC program lab requirements and testing quality measures
<input type="checkbox"/>	Review Ready Set Test!
<p>For more information about PERSONNEL TRAINING/COMPETENCY, refer to CMS: What Do I Need to Do to Assess Personnel Competency</p>	

OTHER LABORATORY CONSIDERATIONS

The components listed below are either CAHC and/or SWP program requirements and best practices. Ask your consultant for assistance and further guidance.

<input type="checkbox"/>	Clinic flow for testing process
<input type="checkbox"/>	Outside billing processes <ul style="list-style-type: none"> • Confidentiality of billing and results
<input type="checkbox"/>	Lab results populating in EHR <ul style="list-style-type: none"> • EHR and parent/guardian portal
<input type="checkbox"/>	Giving test results <ul style="list-style-type: none"> • What method? • When (consider “sensitive” point-of-care test)? • Maintaining confidentiality
<input type="checkbox"/>	Age-appropriate testing considerations
<input type="checkbox"/>	Resolving problems
<input type="checkbox"/>	Recall testing
<input type="checkbox"/>	CAHC Quarterly Reporting of Lab Services
<input type="checkbox"/>	Fiduciary oversight of lab processes <ul style="list-style-type: none"> • Compliance with CLIA requirements • Compliance with OSHA requirements for waste disposal and safety

For more information about CAHC and SWP requirements and best practices regarding OTHER LABORATORY CONSIDERATIONS, refer to:

- CAHC Clinical Laboratory Requirements and Best Practice Considerations (in Laboratory Services Toolkit)
- Laboratory Space Configuration and Storage Guidance (in Laboratory Services Toolkit)
- [CAHC Quarterly Reporting Element Definitions](#)