CATHOLIC HEALTH INITIATIVES®

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Laboratory Compliance Checklist
FY 2016

Date/s	
Location Reviewed	
Primary Contact(s)	**NAME, TITLE OF LABORATORY DIRECTOR** **NAME, TITLE OF LABORATORY COMPLIANCE OFFICER**
Auditor/s	

PART 1 – ENTITY DATA

CONTACT PERSON: LAB DIRECTOR OR DESIGNEE The Laboratory Director may refer you to other individuals to answer the following questions or obtain needed information.

NOTE: The information needed to complete this section should be obtained before the onsite visit.

QUESTION	DESCRIPTION	ADDITIONAL INSTRUCTIONS AND ENFORCEMENT RATIONALE	RESULTS
1-1. Is the name on the laboratory's CLIA and Accreditation licenses the same?	Obtain a copy of the CLIA and Accreditation (If appropriate) licenses and compare name of current director and that which is listed on the licenses. List CLIA Number/Certificate of Registration (For New Labs) and obtain copy of License. Also, document effective dates. List Accreditation identification number and effective dates. NOTE: The Laboratory will be accredited by one agency. (**Check** one) ☐ (CAP) College of American Pathologists ☐ (TJC) The Joint Commission ☐ (AABB) American Association of Blood Banks ☐ COLA ☐ Other (List)	The name on the laboratory's CLIA and Accreditation license must be the same. • If the name on the laboratory's CLIA and Accreditation licenses are not the same, the agencies must be notified within thirty days of the change • If the names are not the same, review documentation submitted to licensing and accrediting agencies informing them of change • Name changes to licensing and accrediting agencies must be made in writing within thirty days of the change. • Document any discrepancies with explanation of difference • **Provide scan of each as an exhibit to file**	

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1-2 How many physical laboratories are overseen by the Laboratory Director? Does each laboratory have its own CLIA license? (List individual CLIA number/s) Does lab leadership understand that each CLIA license in the facility is a separate lab and must be treated as such for proficiency testing purposes?	Obtain a listing of the individual clinical laboratories owned by the entity located either within the entity proper or off campus that are overseen by the Laboratory Director. NOTE: Please consider the main hospital laboratory as one. Also, obtain listing of CLIA licenses. Compare the listings to confirm each laboratory has its own CLIA license. If not describe why. **Scan and attach** the proficiency testing plan for each CLIA laboratory. Besides the actual process for handling the PT specimens, how the specimens will be rotated to different testing personnel, and handled like a patient sample, the policy/plan must also include, at a minimum, the following: • The laboratory must not send proficiency testing samples or portions of such samples to another laboratory for analysis. • The laboratory staff must handle all PT specimens in the same manner as a patient sample. • There may be no inter laboratory communication concerning the PT challenge until after the challenge cutoff date. • PT samples may only be analyzed on primary equipment (Once) and may not be analyzed on secondary equipment until after the challenge cutoff date. (See attached	Any laboratory physically separated located in another building must have its own CLIA License and be treated as such for proficiency testing purposes. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c06.pdf 6008 - *Criteria for One Certification for Multiple Sites*	 CMS Directive FAQs.pdf  PT sampelsecondaryFAQ

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	CMS directive documents) • Any laboratory that receives proficiency testing samples from another laboratory for testing must notify Laboratory leadership who will notify CMS of the receipt of those samples.		
1-3 Determine the subject entity's level of licensure. See descriptions right and select one.	CLIA License is: (**Check one** that applies to this audit) Compile a listing of all CLIA licensed laboratories for which the Administrative director is responsible 1. □ Certificate of Waiver -This certificate is issued to a laboratory to perform only waived tests. 2. □ Certificate for Provider-Performed Microscopy Procedures (PPMP) - This certificate is issued to a laboratory in which a physician, midlevel practitioner or dentist performs no tests other than the microscopy procedures. This certificate permits the laboratory to also perform waived tests. 3. □ Certificate of Registration **-**This certificate is issued to a laboratory that enables the entity to conduct moderate or high complexity laboratory testing or both until the entity is determined by survey to be in compliance with the CLIA regulations. 4. □ Certificate of Compliance- This certificate is issued to a laboratory after an inspection that finds the laboratory to be in compliance with all applicable	Does NOT have to participate in proficiency testing. However if voluntarily participates, describe. Note: The College of American Pathologists (CAP) does require their waived Accredited laboratories to participate in PT. Must participate in proficiency testing. Describe proficiency testing plan. Include copy of procedure . Must participate in proficiency testing. Describe proficiency testing plan. Include copy of procedure. Must participate in proficiency testing. Describe	

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	CLIA requirements. 5. □ Certificate of Accreditation **-**This is a certificate that is issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS.	proficiency testing plan. Include copy of procedure. Must participate in proficiency testing. Describe proficiency testing plan. Include copy of procedure.	
1-4. What is the highest level of testing performed?	Identify the Highest level of testing performed. (**Check one**) a. □ Waived b. □ Moderate c. □ High	Ask the director for this information. The majority of hospital laboratories will be High Complex, Dr offices laboratories will be mostly waived and some moderate which would include physician performed microscopies (PPM).urine microscopic, wet preps,{ferning (OBGYN)}	
1-5. What was the Annual Testing volume (Billable tests) for fiscal year 2015?	Inpatient Outpatient Client **(If available)**	A client is a party with which the clinical laboratory has direct billing agreements.	
1-6.What is the name of the person primarily responsible for laboratory compliance activities?		The entity CRO is rarely this person. The responsibilities are generally assigned to a laboratory staff member or as additional responsibilities of the Administrative Director.	