Please complete all demographic info and answer questions 1 - 14a.				
If the information on the license is not accurate, confirm and document (use box to the right) that appropriate agencies have been notified of change. I.e. new director, moved (Document Correct Information) Note: Licenses are generally not updated immediately, normally updates are made on a two year payment renewal cycle.	Name of Agency notified and date of the notification. List any other comments if necessary:			
CLIA/State License # as it appears on license :				**Questions/Clarifications/Follow-up as needed, please contact:**
Name of Lab as it appears on the CLIA/state license and any correction:	**Yellow Highlight EachTest Done At This Lab**			**Tim Murray**
Lab Address as it appeared on the license and any correction:	**Cholesterol**	**Prothrombin Time**		**Director, Laboratory Compliance**
	Fecal Occult Blood	**Rapid Strep**		**Catholic Health Initiatives**
Red Text = New for FY 2018	**Glucose**	**Sedimentation Rate**		**Ph 610-594-5102**
	Hemoglobin	**Urinalysis Dipstick**		timothymurray@catholichealth.net
Consultant Name (If Any) :	**Hemoglobin AC1**	**Urine Pregnancy**		
Testing personnel Interviewed:	**Hematocrit**	**Others List to Right**		
Name of Laboratory Contact:	**Influenza**			
Laboratory Contact Number:	**Lyme Disease**			Rev 7-17
Date Assessment Completed:	**Ovulation**			
	Place "X "in Box for Answer			
FY 2018 - Waived Testing Assessment	**YES**	**NO**	**N/A**	**Additional guidance and answers to the NON Yes/No questions:**
1.Are all tests performed classified as waived? §§493.15(c), and 493.1775(b)(3)**See below for abbreviated list of waived tests**				
Cholesterol, Fecal Occult Blood, Glucose , Hemoglobin, Hemoglobin A1C, Hematocrit, Influenza, Lyme Disease, Ovulation, Prothrombin Time, Rapid Strep, Sedimentation Rate, Urinalysis Dipstick, Urine Pregnancy				
2. Does the laboratory have the current manufacturer's instructions for all tests performed?				Evidence of Compliance (Click on tab for interpretation.)
3. Does the laboratory follow the current manufacturer's instructions for all tests performed by:				Evidence of Compliance (Click on tab for interpretation.)
a) Using the appropriate specimen?				
b) Adding the required reagents in the prescribed order?				
c) Adhering to the manufacturer's storage and handling instructions?				

d) Using the proper expiration date for the storage method? i.e.Finger stick Glucose controls good for 90 days after open.				
e) Performing the quality control as required by manufacturer?				
f) Performing function checks or calibration?				
g) Performing confirmatory tests as required?				
h)Temp Checks and documents results each day of supply/reagent storage?				
h1)Are there hi/ low acceptable temperature ranges established and documented for each device monitored? Including Room temp if storage requires it?				Evidence of Compliance (Click on tab for interpretation.)
h2)Corrective action if out of range?				
i) Reporting the patients' test results with the terminology or in the units described in the package insert?				
j) Performing and documenting instrument maintenance as described by the manufacturer?				
4. Does the testing personnel understand the manufacturer's instructions for all tests performed?				Use information from 3 above for subjective assessment
5. Does the testing personnel:				
a) Document the name of the test, reagent/control lot number, and expiration date for all tests performed?				Recommended (Evidence of Compliance)
b) Are laboratory personnel given training when they are newly hired?				Please describe i.e. OJT/vendor training
b1)IF answered YES to 5 b, how is the training documented?				
6. Are testing staff:				
a) Observed or evaluated to assure they can provide accurate and reliable testing?				
a1)If answered YES to 6 a, how is the observation/evaluation documented?				
b)Shown how to document the patient's test results?				Evidence of Compliance (Click on tab for interpretation.)
c) Shown how to identify inaccurate results and/or test system or device problems?				
d) Shown how to handle inaccurate results or device problems?				Staff should verbalize that patient results would not be reported until all quality checks are within manufacturers specifications.

7. Are the testing personnel informed when there's a change in the test procedure or if there's a new test kit?				Evidence of Compliance (Click on tab for interpretation.)
a)If answered YES to 7, how is that process documented?				
b) Does the laboratory routinely check incoming package inserts to ensure there have been no changes in the product or procedure?				
c) Are all the products clearly labeled to advise of a revision?				Evidence of Compliance (Click on tab for interpretation.)
8.Have the testing personnel ever been asked to repeat a waived test?				
a)If yes, was the second result different than the original result?				
b)If the second result was different from the first result, what result did the physician use?				
9. Does the laboratory phlebotomy/testing staff:				
a) Check patient identification?				Conversation confirms that two patient identifiers must be used
a1)Is there a written procedure?				Best practice
b) Collect the proper specimen for the test requested?				Evidence of Compliance (Click on tab for interpretation.)
b1)Are All blood collection supplies, tubes,needles, alcohol preps in date? Stored at appropriate temperature?				Check dates on supply in phlebotomy and bulk storage areas . Are storage temperatures prescribed by the manufactuer being observed?
b2)Is there a written procedure?				Best practice not required
c) Require a Lab order (On patient's chart or hard copy) before performing a test?				Evidence of Compliance (Click on tab for interpretation.)
c1) Is the order kept 7 years?				
d) Maintain a log or record of laboratory tests performed?				Not required but should be able to verbalize how they would investigate a manufacturers' recall of a product
e) Maintain a log or record of quality control results for each waived test instrument?				Evidence of Compliance (Click on tab for interpretation.)
e1)Does testing staff look at numeric Quality Control results for shifts and trends daily and on an ongoing basis?				
f) Keep the patient's test report in the patient's chart?				
10. Does the laboratory use any waived test kits that require additional confirmatory procedures? (Need to Send out or perform another test in house)				Give example if yes
11. Does the laboratory send the specimen out to another laboratory to meet the additional requirement?				

a)If the specimen is sent out to meet the additional requirements, does the laboratory report results prior to receiving the confirmation report?				Explain situation
b)Are the results of the confirmatory test documented in the patient's chart?				
12. Does the laboratory staff identify:				
a) Instrument or device error codes?				
b) Internal or electronic (procedural) quality control failure?				
c) External (liquid) quality control failure?				
d) Proficiency testing failure? If appropriate.				
e) Test results not correlating with patient's symptoms or history?				
13. Are the laboratory's results timely? Timely= ordering physician satisfied with turn around time				
14. Is the laboratory voluntarily enrolled in proficiency testing?				Not required unless accredited by CAP (College of American Pathologists)
14a) If 14 is yes, please list the name of the proficiency testing company(ies).				

Evidence of Compliance

Red= extra emphasis and review

Question Number

2. Ask interviewee to show you the current package insert and demonstrate how he/she knows that is most current.

3. Choose a representative test ask the interviewee to walk through the procedure with you and point out the items listed in lines 3a-j

Look at Test Kit and individual components and controls and check to see that all are within expiration date

Look at control results and confirm that they are within the manufacturer's expectations: Controls may have a shorter expiration after opened. i.e. fingerstick glucose controls are good for 90 days after opening

Look at temperature records and compare to manufacturer's storage requirements (room temp, refrigerated and frozen where appropriate) Recommend that acceptable temp ranges be included on documentation chart

If any of the above are not within expected parameters investigate what the corrective action was and review with interviewee the follow-up actions. (See below)

I.e. Patients not reported, called manufacturer to troubleshoot, told supervisor/lab director, If temperatures were off, moved specimens/reagents to an acceptable temperature controlled area

5a. Separate documentation of this information is not required but ask how the lab would handle identifying patients tested using a recalled defective test kit?

6b,c,d. Ask interviewee to demonstrate how results are entered/documented in patient chart, How they would troubleshoot bad controls or instrument readings?

7. Testing staff should verbalize that they review each new kit instructions for changes or that their supervisor informs and educates them of new changes. Someone MUST review each new insert for changes. (Best practice documents that fact)

9b. Ask staff to show you in the manufacturer's insert where the manufacturer describes the correct specimen to collect for analysis.

9c. Ask testing staff to show you evidence of a typical test order.

9e.Log is not required (Best Practice) but interviewee needs to be able to verbalize how to confirm to an inspector or the laboratory medical director that controls were acceptable after the fact (days, weeks later)