Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0663536	07/02/2021
Name of Provider or Supplier	**Street Address, City, State**	
Louisiana Office Of Public Health Laboratory	1209 Leesville Ave, Baton Rouge, LA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Federal Jurisdictional Recertification Survey The laboratory is in compliance with the CLIA regulations with standard level deficiencies cited.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on manufactures package insert, a review of policies and procedures, and interview with staff the laboratory failed to ensure their written policies were consistent with the manufacturer storage requirements for HAVAB samples. a. A review of the Architect System HAVAB-M (G6-5290/R05), page 3, revealed "Specimen Collection and Preparation For Analysis ...Storage: Specimens may be stored ...up to 3 days at room temperature (study performed at 21-30C)". b. A review of the Architect System HAVAB-G (G4-5668/R03), page 3, revealed "Specimen Collection and Preparation For Analysis ...Storage: Specimens may be stored ...up to 4 days at room temperature." c. A review of the laboratory's procedure Standard Operating Procedure HAVAB-M (Qualtrax ID: 6125, Revision: 3) published 06/28 /2021 pages 2-3, revealed "Specimen Information" revealed no room temperature storage criteria. d. A review of the laboratory's procedure Standard Operative Procedure HAVAB-G (Qualtrax ID: 7480, Revision 2) published 06/21/2021, page 2, revealed "Specimen Information ...Specimen stability and storage requirements ... Store and ship at room temperature for up to 4 days." The laboratory did not define range for room temperature storage. e. General Supervisor 3 provided the laboratory's

	Room Temperature and Humidity Requirements form that included "Department: Virology/Serology ...Room #: B105.04 ...Acceptable Temperature Range for this Room/Location: 15-30C." The range was inconsistent with manufacturer's requirements for Architect System HAVAB-M (21-30C). f. An interview with Testing Personnel 11 (see CMS-209 form) on 06/30/2021 at 10:32 AM revealed the laboratory's HAVAB testing volume is approximately 1 sample every 3 weeks. g. An interview with General Supervisor 3 (see CMS-209 form) on 07/01/2021 at 1:52 PM confirmed the findings. *Acronyms: HAVAB= Hepatitis A Virus, HAVAB-M=Hepatitis A Virus Antibody Immunoglobulin M, HAVAB-G= Hepatitis A Virus Antibody Immunoglobulin G, C=degree Celsius.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on manufacturer's instructions, review of policies and procedures, and interview with staff the laboratory failed to ensure calibration material for the BD MGIT 960 was not used when it had exceeded the expiration date. a. A review of BD BACTEC MGIT User Manual (Revision 16, Version G) page 93 revealed "6.2.2.2 Calibrator Replacement ...Calibrator tubes ...must be replaced prior to their expiration." b. A review of the laboratory's Opportunity For Improvement (OFI) Form revealed the following: 1. OFI # 1901020: "During a PM performed on the BACTEC MGIT 960 (SN#MG4032) by a BD Service Representative on 1/8/2019, the service representative noted that the onboard MGIT calibrators (Lot#: 6266913/Exp: 9/12 /2018) were expired. This expired lot of calibration tubes was used by the instrument to perform hourly calibration checks from 9/22/2018 through the date that the expired calibrators were replaced on 1/14/2019." 2. OFI # 2011022: "On 11/13/2020 the calibrators onboard the BD MGIT 960 expired." c. A review of the laboratory procedure Digestion, Decontamination, Smear Preparation Media Inoculation (Qualtrax ID: 4233, revision 5) published 05/07/2021, page 3, revealed "Quality Control1.b.Positive Control ...This control may also be run daily in parallel with the negative process control in the event that an expired calibrator is in use onboard the BD MGIT 960 ...." d. An interview with the Laboratory Director on 07/01/2021 at 11: 00 AM confirmed the laboratory used expired calibrators.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials

	having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on direct observation, a review of quality control data, and interview with staff, the laboratory failed to establish acceptable quality control criteria for the Treponema Assay (Syphilis): Syphilis IgG/IgM assay performed on the Diasorin for 6 of 6 lots number (11/2019 through 07/2021). a. On 06/30/2021 at 10:32 AM in Virology the Survey observed 2 Diasorin instruments (Serial Numbers 2210003400 and 2210003534). b. A review of the Syphilis Control QC Using Historical Standard Deviation forms from 11/08/2019 to 07/01/2021 revealed the laboratory established a single "shared" mean based on data point from both instruments. c. A review of the Syphilis LJ Monitoring Chart forms from 11/08/2019 to 07/01/2021 revealed the laboratory monitored quality control for both instruments against an established "shared" mean and showed each instrument had a distinct bias. d. In interview with the Virology Technical Supervisor and the General Supervisor 3 (see CMS-209 form) on 07/01/2021 at 2:24 PM confirmed the laboratory's method for establishing and evaluating Syphilis quality controls, the current method does not allow for instrument bias, and the laboratory's total test volume from 11/08/2019 to 7/1/2021 was 28,685.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of 10 patient test reports, the laboratory's policy, manufacturer's instructions, interview with the laboratory director and quality assurance specialist, the laboratory failed to follow manufacturer's instructions and their policy for reporting EUA APTIMA SARS CoV-2 patient test results in April ,May, June 2021 as evidenced by: 1. According to manufacturer's instructions pg 22 under Interpretation of Results, a table is provided which outlines how test results should be reported on the final report. Based on this table, it states "SARS-CoV-2 result neg or POS" 2. In review of the laboratory's policy titled, "Aptima SARS CoV-2 on Panther" a table is provided which outlines how test results should be reported on the final report. Based on this table, it states "SARS-CoV-2 result neg or POS" 3. In review of the following 10 patient test reports, the laboratory did not report the actual result of the test as either neg or POS as stated in their policy and manufacturer's instructions. 1. received on 5/2/2021 patient #332552 2. received on 5/4/2021 patient #340330 3. received on 5 /12/2021 patient #3378026573 4. received on 5/14/2021 patient #36638 5. received on 6/14/2021 patient #4720 6. received on 4/21/2021 patient #213208029 7. received on 4 /14/2021 patient #59872 8. received on 4/26/2021 patient #6913 9. received on 6/2 /2021 patient# LA2020729310 10. received on 6/9/2021 patient # 337895 4. In interview with both the Laboratory Director and Quality Assurance specialist on 6/30

	/2021 @ 1313 stated that they were unaware of the manufacturer's requirements. The also believe the policy was reflective of the manufacturer's instructions. They did not know that they had to also report out neg or POS on the patient test report.