Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0663536	04/06/2023
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	Complaint Investigation 4/4/2023 to 4/6/2023: The complaint was found unsubstantiated with no deficiencies cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure, laboratory's cutoff data documents, and interview with the Technical Supervisor, the laboratory failed to follow their procedure for their yearly review of adjusting and/or calculating new Newborn Screening cutoff points for 2021 to the date of the survey as evidenced by: 1. In review of the laboratory's procedure, titled "Procedure for Monitoring Cuttoff Values for Newborn Screening Neonatal Assay" states, "The data set will be monitored by continuously expanding the data range of samples analyzed to be inclusive of all data analyzed since the establishment of the new cutoff values. The data set is monitored monthly for up to one year; thereafter, the dataset will be reevaluated on a yearly basis." 2. In review of the laboratory cutoff data documents, for the following newborn screening assays, the laboratory did not review or recalculated the cutoffs for each assay on a yearly basis. a. C14:1 reviewed on 2/23/2018 b. C16 + C18 reviewed on 8/27/2018 c. CO/ (C16 + C18) reviewed in 2015 d. C3 reviewed in 2015 e. C3/C2 reviewed in 2015-2016 f. C3DC C4OH reviewed in 2015-2016 g. C4 reviewed in 2015-2016 h. C5 reviewed in 2015-2016 i. C5/C3 reviewed in 2015-2016 j. C5:1 reviewed in 2015-2016 k. C5DC_C6OH/C8 reviewed in 2015-2016 l. C8 reviewed in 2015-2016 m. C10 reviewed in 2015-2016 n. C10:1 reviewed in 2015-2016 o. C10:2 reviewed in 2015-2016 p. C8/C10 reviewed in 2015-2016 q. C14:1 reviewed in 2015-

	2016 r. C14:1/ C12:1 reviewed in 2015-2016 s. C14:2 reviewed in 2015-2016 t. C18:1 reviewed in 2015-2016 u. Ala reviewed on 11/27/2017 v. Arg reviewed in 2015-2016 w. Arg/Orn reviewed in 2015-2016 x. Val reviewed in 2015-2016 y. Cit reviewed in 2015-2016 z. Cit/Arg reviewed in 2015-2016 aa. Leu reviewed in 2015-2016 bb. Leu /Ala reviewed in 2015-2016 cc. Leu/Phe reviewed in 2015-2016 dd. Met/Phe reviewed in 2015-2016 ee. SUAC reviewed in 2015-2016 3. In interview with the Technical Supervisor on 4-6-2023 at 1348, he stated that the laboratory had not looked at the assays cutoffs annually and that it had been several years since they reviewed them.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, patient instrument reports, final patient reports, and interview with the Technical Supervisor(s), the laboratory failed to follow its IQCP for the BioFire FilmArray Gastrointestinal panel (GI) for 6 of 6 months from February 2022 through March 2023. Findings included: a. A review of the laboratory's Individualized Quality Control Plan (IQCP) for the Biofire GI Assay revealed, " ... external surrogate sample controls will continue to be performed for each new lot number or shipment of test materials or every 31 days, whichever is more frequent." b. The laboratory had four BioFire Film Array instruments used for testing (Serial Numbers (SN): 2FA02477, 2FA02652, 2FA05764, and 2FA05947) and their QC program required the following control material be performed on the BioFire Film Array instrument: External Control Maine Molecular Quality Controls, Inc (MMQCI) M239 which detected the following: Clostridium difficile toxin A/B, Plesiomonas shigelloides, Vibrio, Vibrio cholerae, Yersinia enterocolitica, Enteroaggregative E. coli (EAEC), Shiga-like toxin-producing E. coli (STEC) stx1/stx2, Shigella /Enteroinvasive E. coli (EIEC), Cryptosporidium, Adenovirus, F 40/41, Sapovirus. MMQCI M240 which detected the following: Campylobacter, Salmonella, Enteropathogenic E. coli (EPEC), Enterotoxigenic E. coli (ETEC) It/st, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia, Astrovirus, Norovirus GI/GII, Rotavirus A. External Control Blank (Uninoculated Cary-Blair media). No organisms detected. Campylobacter, Clostridium difficile toxin A/B, Plesiomonas shigelloides, Salmonella, Vibrio, Vibrio cholerae, Yersinia enterocolitica, Enteroaggregative E. coli (EAEC), Enteropathogenic E. coli (EPEC), Enterotoxigenic E. coli (ETEC) It/st, Shiga-like toxin-producing E. coli (STEC) stx1/stx2, Shigella/Enteroinvasive E. coli (EIEC), Cryptosporidium, Cyclospora cayetanensis, Entamoeba histolytica, Giardia lamblia, Adenovirus, F 40/41, Astrovirus, Norovirus GI/GII, Rotavirus A, Sapovirus. c. Review of patient results from February 2022 through March 2023, revealed the laboratory failed to perform all external surrogate control (per their IQCP) on each instrument prior to analysis and reporting of patient final results, as follows: Date: 02

	/02/2022 BioFire SN: 2FA02477; The laboratory failed to perform external control blank, M239, and M240 QC. Patient Sample ID#: N22013072 was analyzed and reported on 02/25/2022. BioFire SN: 2FA05764; The laboratory failed to perform external control blank and M239 QC. Patient Sample ID#: N22013074 was analyzed and reported on 02/25/2022. BioFire SN: 2FA05947; The laboratory failed to perform external control blank and M240 QC. Patient Sample ID#: N22013075 was analyzed and reported on 02/25/2022. Date: 02/03/2022 BioFire SN: 2FA02652; The laboratory failed to perform M239 and M240 QC. Patient Sample ID#: N22013073 was analyzed and reported on 02/25/2022. Date: 04/28/2022 BioFire SN: 2FA02477; The laboratory failed to perform external control blank, M239, and M240 QC. Patient Sample ID#: N22026617 was analyzed on 04/28/2022 and reported on 04/29/2022. Patient Sample ID# N22026113 was analyzed and reported on 04/28/2022. Date: 06 /20/2022 BioFire SN: 2FA05947; The laboratory failed to perform external control blank and M239 QC. Patient Sample ID#: N22036745 was analyzed on 06/20/2022 and reported on 06/23/2022. Date: 08/01/2022 BioFire SN: 2FA02652; The laboratory failed to perform M239 and M240 QC. Patient Sample ID#: N22039965 was analyzed 08/01/2022 and reported on 10/10/2022. BioFire SN: 2FA05764; The laboratory failed to perform external control blank and M239 QC. Patient Sample ID#: N22043998 was analyzed on 08/01/2022 and reported on 10/03/2022. Date: 12 /01/2022 BioFire SN: 2FA02477; The laboratory failed to perform external control blank and M240 QC. Patient Sample ID#: N22069273 was analyzed and reported on 12/01/2022. Patient Sample ID#: N22071298 was analyzed and reported on 12/09 /2022. BioFire SN: 2FA02652; The laboratory failed to perform M239 and M240 QC. Patient Sample ID#: N22071299 was analyzed and reported on 12/09/2022. Date: 03 /23/2023 BioFire SN: 2FA02652; The laboratory failed to perform M239 QC. Patient Sample ID#: N23019218 was analyzed and reported on 03/23/2023. Date: 03/28 /2023 BioFire SN: 2FA02652; The laboratory failed to perform external control blank QC. Patient Sample ID#: N23019964 was analyzed and reported on 03/28/2023. BioFire SN: 2FA05947; The laboratory failed to perform M239 and M240 QC. Patient Sample ID#: N23019966 was analyzed and reported on 03/28/2023. Patient Sample ID#: N23019965 was analyzed and reported on 03/28/2023. The laboratory did not include M239, M240, and External Control Blank on each BioFire instrument (every 31 days) prior to patient testing. d. An interview on 04/06/2023 at 9:20 AM in conference room B201 with Technical Supervisors 1 and 2, as listed on the CMS-209, confirmed the findings.