Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0457593	05/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Pediatric Clinic - Westbank	151 Ochsner Blvd, Suite F, Gretna, 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	A Recertification survey was performed on May 16, 2022 at Pediatric Clinic Westbank, CLIA ID # 19D0457593. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS 209 form, proficiency test records, laboratory policies, and interview with personnel, the laboratory failed to ensure the Laboratory Director signed the attestation statement for one (1) of six (6) proficiency testing (PT) events reviewed. Findings: 1. Review of the laboratory's CMS 209 (Laboratory Personnel Report) form revealed the Laboratory Director also serves as the laboratory's Technical Consultant. 2. Review of the laboratory's "Monthly Q/A Discussion Checklist" revealed the following monitors: a) Personnel polices: which included, but not limited to "Do personnel follow the manufacturer's guidelines for test performance and troubleshooting? Check the Lab Personnel Evaluation Checklists: Testing personnel are evaluated at six months after beginning patient testing and then at least annually thereafter." b) Proficiency testing policies c) Safety and environmental policies: which included but not limited to "Test materials were stored as directed by the manufacturer. All outdated materials were discarded and not used for patient testing." d) Preanalytical testing policies e) Analytic testing policies f) Postanalytical procedures 3. Review of the laboratory's American Proficiency Institute (API) records for 2020, 2021, and 2022 revealed the Laboratory Director did not sign the attestation statement for the following events: 2022 Hematology/Coagulation 1st

	Event 2022 Chemistry Miscellaneous 1st Event 4. In interview on May 16, 2022 at 11: 30 am, the Manager confirmed the Laboratory Director did not sign the identified PT attestation statements.
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 observation by surveyor, review of laboratory's policies, and interview with personnel, the laboratory failed to ensure supplies did not exceed expiration date. Findings: 1. Observation by surveyor during the laboratory tour on May 16, 2022 at 9: 38 am revealed the following expired items: Consult Diagnostics Immunochemical Fecal Occult Blood Test, Lot 1219111, Expiration Date: 2021-10-31, Quantity: one (1) box 2. Review of the laboratory's "Monthly Q/A Discussion Checklist" revealed the following monitors: a) Personnel polices: which included, but not limited to "Do personnel follow the manufacturer's guidelines for test performance and troubleshooting? Check the Lab Personnel Evaluation Checklists: Testing personnel are evaluated at six months after beginning patient testing and then at least annually thereafter." b) Proficiency testing policies c) Safety and environmental policies: which included but not limited to "Test materials were stored as directed by the manufacturer. All outdated materials were discarded and not used for patient testing." d) Preanalytical testing policies e) Analytic testing policies f) Postanalytical procedures 3. In interview on May 16, 2022 at 10:01 am the Manager stated the occult blood test was discontinued December 31, 2019. The Manager confirmed the identified test kits were expired.
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 observation by surveyor, review of manufacturer's instructions, patient final test reports, test menu, and interview with personnel, the laboratory failed to include the the Food and Drug Administration (FDA) Emergency Use Authorization statement on SARS COV-2 patient final reports. Findings: 1. Observation by surveyor during the laboratory on May 16, 2022 at 9:38 am revealed the laboratory utilizes the Abbott ID Now for SARS COV-2 testing. 2. Review of the manufacturer's instructions revealed "This product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization (EUA) for use by

	authorized laboratories." 3. Review of the following random patient final test report for SARS COV-2 revealed the laboratory did not include the identified Emergency Use Authorization statement on the patient final report: Patient 12534.2 4. In interview on May 16, 2022 at 11:12 am , the Manager confirmed the laboratory's patient final reports for SARS COV-2 did not include the identified statement. 5. Review of the laboratory's test menu revealed the laboratory performs 4,398 SARS COV-2 tests annually.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory's policies, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5417.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure proficiency samples are tested as required. Refer to D2009.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, personnel records, and interview with personnel, the Technical Consultant failed to perform a competency assessment semi-annually during the first year for one (1) of four (4) testing personnel reviewed. Findings: 1. Review of the laboratory's personnel records revealed the laboratory hired four (4) new testing personnel since their previous survey on February 18, 2020. 2. Review of the "Laboratory Personnel Competency" policy dated April 12, 2020 revealed "The testing personnel will be evaluated for competency 6 months after patient testing begins using a Competency checklist and then annually thereafter." 3. Review of the laboratory's "Monthly Q/A Discussion Checklist" revealed the following monitors: a) Personnel polices: which included, but not limited to "Do personnel follow the manufacturer's guidelines for test performance and troubleshooting? Check the Lab Personnel Evaluation Checklists: Testing personnel are evaluated at six months after beginning patient testing and then at least annually thereafter." b) Proficiency testing policies c) Safety and environmental policies: which included but not limited to "Test materials were stored as directed by the manufacturer. All outdated materials were discarded and not used for patient testing." d) Preanalytical testing policies e) Analytic testing policies f) Postanalytical procedures 4. Further review of the laboratory's personnel records revealed Testing Personnel 5 (hired August 6, 2020) did not have documentation of a semi-annual competency assessment due February 2021. 5. In interview on May 16, 2022 at 10:42 am, the Manager stated the laboratory thought a semi-annual competency assessment was not needed for Testing Personnel 5. The Manager further stated Testing Personnel 5 was a previous employee who left in December 2019 and rehired August 6, 2020. The Manager confirmed a semi-annual competency assessment was not performed for Testing Personnel 5.