Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0460199	11/30/2020
Name of Provider or Supplier	**Street Address, City, State**	
Children's Medical Center	71107 Hwy 21 Suite 1, Covington, 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 Certification Survey was performed at Children's Medical Center-CLIA # 19D0460199 on November 30, 2020. Children's Medical Center was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director 42 CFR 493.1421 CONDITION: Laboratories perfoming moderate complexity testing; Testing Personnel
D1002	REPORTING OF SARS-CoV-2 TEST RESULTS During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of the laboratory's COVID reports and interview with personnel, the laboratory failed to report seventy two (72) negative COVID results to the state as required. Findings: 1. In interview on November 30, 2020 at 9:02 am, Testing Personnel 1 stated the laboratory began testing COVID samples on the Abbott ID Now on October 19, 2020 and ended November 19, 2020 because they ran out of kits. 2. In further interview on November 30, 2020 at 9:03 am, Testing Personnel 1 stated positive results were reported to the state. Testing Personnel 1 stated she was unaware that negative results needed to be reported. 3. Review of the laboratory's COVID 19 patient log revealed the laboratory did not report the following patients to the state as required: Total of seventy two (72) patients: Patient 4188 Patient 5476 Patient 3429 Patient 2254 Patient 2660 Patient 2687 Patient 18 Patient 1277
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)

	All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records, policies and procedures, and interview with personnel, the laboratory failed to perform an assessment for two (2) of six (6) proficiency testing (PT) events. Findings: 1. Review of the laboratory's "Policy Procedure Manual" revealed "When the results of the PT come in they are signed by the general supervisor. If corrective action needs to be taken it will be done at that time When receiving P.T. back if less that 100% we see what corrective action needs to be done and list it on our corrective action sheet." 2. Review of the laboratory's 2019 and 2020 ACP Medical Laboratory Evaluation PT results for Hematology revealed the laboratory received the following unacceptable results: a) 2019 2nd Event Cell Identification or WBC Differential Score 93 %: Sample HD-6 for Granulocytes/Neutrophils b) 2020 3rd Event Red Blood Cell Count (Score 80%), Hematocrit (Score 80%), and Hemoglobin Score (80%): Sample HD-14 3. Review of the laboratory's PT records revealed the laboratory did not perform assessments for the identified unacceptable results. 4. In interview on November 30, 2020 at 1:24 pm, Testing Personnel 1 stated she thought if everything passed nothing further needed to be done. Testing Personnel 1 confirmed the laboratory did not perform an assessment for the identified PT events.
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 policies and procedures, instrument printouts, patient final reports, and interview with personnel, the laboratory failed to follow their policy for Complete Blood Count (CBC) flags for nine (9) of ten (10) patients reviewed. Findings: 1. Review of the laboratory's "Procedure Manual Complete Blood Count (CBC)" policy revealed "When a flagging issue occurs the following methods or action will be required by the staff: Look up the indicator code in the Medonic M Series Manual (pages 69-74) and follow the required action. The personnel will redraw and run another CBC and then alert the ordering physician and will follow his recommendation. Example: Repeat in several days, send child to the hospital for further evaluation." 2. Review of the Medonic manual revealed the following actions for flags: a) "BD: WBC DIFF: High interference between populations. Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." b)" OM: WBC DIFF: Only one WBC population found; slide review advised. Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results." 3. Review of random selection of ten (10) patients with flags in November 2020 revealed the laboratory did not follow their CBC flag policy for the following nine (9) patients : November 3, 2020: Patient 2677: Flag OM for LYM, MID, GRAN, LYM %, MID%, and GRA%; "WBC Diff: Only one WBC population found; slide review advised. The laboratory did not repeat CBC test. November 5, 2020: Patient 4623:Flag OM for LYM, MID, GRAN, LYM %, MID%, and GRA%;

	"WBC Diff: Only one WBC population found; slide review advised. The laboratory did not repeat CBC test. November 10, 2020: Patient 4983: Flag OM for LYM, MID, GRAN, LYM %, MID%, and GRA%; "WBC Diff: Only one WBC population found; slide review advised. The laboratory did not repeat CBC test. November 11, 2020: Patient 4446: Flag BD for LYM, MID, GRAN, LYM%, MID%, GRA%; BD-WBC Diff: High interference between populations" Patient 4639: Flag OM for LYM, MID, GRAN, LYM %, MID%, and GRA%; "WBC Diff: Only one WBC population found; slide review advised. The laboratory did not repeat CBC test. November 12, 2020: Patient 5039: Flag OM for LYM, MID, GRAN, LYM %, MID%, and GRA%; "WBC Diff: Only one WBC population found; slide review advised. The laboratory did not repeat CBC test. Patient 2023: Flag OM for LYM, MID, GRAN, LYM %, MID%, and GRA%; "WBC Diff: Only one WBC population found; slide review advised. The laboratory did not repeat CBC test. November 19, 2020: Patient 4658: Flag OM for LYM, MID, GRAN, LYM %, MID%, and GRA%; "WBC Diff: Only one WBC population found; slide review advised. The laboratory did not repeat CBC test. Patient 4676: Flag OM for LYM, MID, GRAN, LYM %, MID%, and GRA%; "WBC Diff: Only one WBC population found; slide review advised. The laboratory did not repeat CBC test. 4. In interview on November 30, 2020 at 1:47 pm, Testing Personnel 1 stated she does not always have enough sample to rerun. The Testing Personnel 1 confirmed the laboratory did not follow their CBC flag policy for the identified patients.
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 during laboratory tour and interview with personnel, the laboratory failed to ensure supplies did not exceed their expiration dates. Findings: 1. Observation by surveyor during laboratory tour on November 30, 2020 revealed the following expired items: a) Binax Now RSV Card, Lot 103485, Expiration date:2020-08-28, Quantity: one (1) kit b) BD Eclipse Needle 21 G, Lot 4323466, Expiration date:2019-11, Quantity: two (2) needles c) BD Eclipse Needle 21 G, Lot 9287174, Expiration date: 2014-10, Quantity: three (3) needles d) BD Eclipse Needle 21 G, Lot 1325710, Expiration date: 2106-11, Quantity: three (3) needles e) Amies Transystem, Lot 181646700, Expiration date: 2020/01, Quantity: one (1) tube f) Ethanol Solution 70%, Lot 7081, Expiration date: 2019-03-22, Quantity: one (1) bottle g) Alere i Influenza A and B Control Swab Kit, Lot 093757, Expiration date: 2019-11-28, Quantity: one (1) kit 2. In interview on November 30, 2020 at 9:40 am, Testing Personnel 1 confirmed the identified items were expired.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The

	laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, quality control records, and interview with personnel, the laboratory failed to perform corrective action for unacceptable quality control samples for Complete Blood Count (CBC) testing. Findings: 1. Review of the laboratory's "Policy Procedure Manual" revealed "Controls are run in the morning before any patients are run. We run a low normal and high in the morning and the afternoon. If in the morning the self test has failed it is repeated." 2. Review of the laboratory's "Quality Assurance Program" procedure revealed "Quality Control-Done daily and twice daily on some parameters. Be sure all test are within range and check to see if QC is being done on all test done daily." 3. Review of the laboratory's quality control (QC) records for January 2019, February 2020, and October 2020 revealed QC was unacceptable on February 28, 2020: Normal control: RBC reported 4.34 x 10 12/l , flag : H (Acceptable range 3.96-4.32). 4. Further review of the laboratory's CBC QC records revealed the laboratory did not perform corrective actions for the identified date. 5. Review of patient logs for the identified date revealed the following patients were reported without corrective action: Patient 636 Patient 3206 6. In interview on November 30, 2020 at 11:00 am, Testing Personnel 1 stated the identified QC was not repeated. Testing Personnel 1 confirmed the identified patients were reported without corrective action for unacceptable QC.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. Review of the laboratory's "Quality Assurance Program" policy revealed "This program is designed to monitor and evaluate the ongoing and overall quality of the total testing process (preanalytic, analytic, post analytic)." 2. Further review of the laboratory's "Quality Assurance Program" revealed the following issues within the analytic system were not identified: a) The laboratory failed to follow their policy for Complete Blood Count (CBC) flags for nine (9) of ten (10) patients reviewed. Refer to D5401. b) The laboratory failed to ensure supplies did not exceed their expiration dates. Refer to D5417. c) The laboratory failed to perform corrective action for unacceptable quality control samples for Complete Blood Count (CBC) testing. Refer to D5783.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance

	with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyor during laboratory tour, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 2. The Laboratory Director failed to ensure the laboratory performed corrective action for unacceptable proficiency testing results. Refer to D6019. 3. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6021. 4. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's quality control limits occurred. Refer to D6024. 5. The Laboratory Director failed to ensure Nurse Practitioner 1 met educational requirements for moderate complexity testing. Refer to D6029. 6. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established and maintained. Refer to D6030.
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, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to follow their policy for Complete Blood Count (CBC) flags for nine (9) of ten (10) patients reviewed. Refer to D5401. 2. The laboratory failed to ensure supplies did not exceed their expiration dates. Refer to D5417.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory performed corrective action for unacceptable proficiency testing results. Refer to D5221.

D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5793.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's quality control limits occurred. Refer to D5783.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure Nurse Practitioner 1 met educational requirements for moderate complexity testing. Refer to D6065.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)

	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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were established and maintained. Findings: 1. The Technical Consultant failed to ensure procedure to assess personnel competency were complete. Refer to D6046. 2. The Technical Consultant failed to evaluate competency annually for two (2) Nurse Practitioners performing moderate complexity testing. Refer to D6054.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of personnel competency records and interview with personnel, the Technical Consultant failed to ensure procedures to assess personnel competency were complete. Findings: 1. Review of the laboratory's "Pre-Analytic Competency Assessment" form revealed an assessment performed at six months and annually for the following five (5) of the six (6) minimal assessment criteria: a) "Direct observation of test performance b) Monitoring test results, records, and reporting c) Review of records, worksheets, QC, PT, and maintenance d) Direct observation of instrument maintenance/function checks e) Evaluation of knowledge and problem solving skills" 2. Further review revealed the laboratory did not include the sixth requirement "assessment of test performance through testing preciously analyzed specimens, internal blind testing samples or external proficiency testing sample" as a criteria. 3. Review of the laboratory's "Lab Performance Log" revealed the following information included: Test name:"CBC, U/A, RSV, Mono, M Flu, Strep, Covid, UPT, Flu AB, Lipid and License and CME" 4. Review of the 2019 and 2020 competency assessment records for Testing Personnel 1 revealed the laboratory utilized the "Lab Performance Log" that did not include the identified six (6) minimum assessment criteria for the Complete Blood Count (CBC) tests. 5. In interview on November 30, 2020 at 1:34 pm, Testing Personnel 1 stated the laboratory utilized the "Lab Performance Log" to document competency assessment.
D6054	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 annually, after the first year. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the Technical Consultant failed to evaluate competency annually for two (2) Nurse Practitioners performing moderate complexity testing. Findings: 1. In interview on November 30, 2020 at 10:44 am, Testing Personnel 1 stated Nurse Practitioner 1 and Nurse Practitioner 2 perform Complete Blood Count (CBC) testing. 2. Review of the personnel records for Nurse Practitioner 1 and Nurse Practitioner 2 revealed the laboratory did not have documentation of an annual competency assessment for 2019 and 2020. 3. In further interview on November 30, 2020 at 1:34 pm, Testing Personnel 1 stated she thought Nurse Practitioners were exempt from competency assessments. Testing Personnel 1 confirmed annual competency assessments were not performed for Nurse Practitioner 1 and Nurse Practitioner 2.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review and interview with personnel, the laboratory failed to provide documentation to ensure all testing personnel met education requirements. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of personnel records and interview with personnel, the laboratory failed to provide documentation that one (1) of four (4) testing personnel reviewed met the educational qualifications for performing moderate complexity testing. Findings: 1. Review of personnel records revealed the laboratory did not not maintain documentation of at least a High School Diploma or equivalent for Nurse Practitioner

	1. 2. In interview on November 30, 2020 at 3:05 pm, Testing Personnel 1 confirmed the laboratory did not have documentation of education for Nurse Practitioner 1.