Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0315529	10/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Children's Clinic Pa Of West Tennessee, The	264 Coatsland Dr, Jackson, TN	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, competency assessment documents, and interview with the lead testing personnel, the laboratory failed to have a policy/procedure for testing personnel competency assessment in 2018 and 2019. The findings include: 1) Review of the laboratory procedure manual revealed no policy/procedure for testing personnel competency assessment. 2) Review of the laboratory's Centers for Medicare and Medicaid Services form 116 (CMS 116) revealed the laboratory performs the following testing: Total and Direct Bilirubin, Wet Prep, KOH prep, Urine Microscopy, and Complete Blood Count (CBC). 3) Review of the laboratory's competency assessment form revealed competency assessments performed, with no indication of which test systems the competency was performed for. 4) Interview with the lead testing personnel on October 11, 2019 confirmed the laboratory does not have a policy/procedure for testing personnel competency and the current competency assessment form does not indicate which test systems competency was performed for.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)

	(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of laboratory records, and interview with the lead testing personnel, the laboratory failed to verify the performance of the Advanced Instruments Bilirubinometer BR2 instrument used for performing Total and Direct Bilirubin in 2018. The finding include: 1) Observation of the laboratory on October 11, 2019 at 8:45 am revealed the Advanced Instruments Bilirubin Stat-Analyzer (serial number 17040348C) on the counter in use for patient testing for total and direct bilirubin. This instrument serial number was new since the last survey. 2) Review of laboratory records revealed no verification of performance specifications for the new bilirubin instrument were present. 3) Interview with the lead testing personnel confirmed no records were available verifying the performance specifications for the Advanced Instruments Bilirubinometer. The laboratory uses the Advanced Instrument Bilirubinometer for patient testing for total and direct bilirubin, and began using the instrument sometime early 2018.
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 review of the laboratory's proficiency testing records, the laboratory's quality assurance plan, and interview with the lead testing personnel, the laboratory director failed to ensure an approved corrective action plan was followed for unacceptable proficiency testing results in 2019. The findings include: 1) Review of the laboratory's proficiency testing records revealed unacceptable results for Direct Bilirubin for sample number NB-01, 2019 event NB-A. The report was signed by both the lead testing personnel and the laboratory director. 2) Review of the laboratory's quality assurance plan revealed that any deficiencies in proficiency testing will be investigated and corrective action taken. 3) Interview with the lead testing personnel on October 11, 2019 at 3:00 p.m. confirmed the laboratory director failed to ensure the laboratory's plan was followed for unacceptable proficiency testing scores in 2019.
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 review of testing personnel records and interview with the lead testing personnel, the laboratory director failed to ensure testing personnel number one had appropriate documentation of education in 2018 and 2019. The findings include: 1) Review of the testing personnel records revealed no documentation of the highest level of education for testing personnel number one. Date of hire was July 23, 2018. 2) Interview with the lead testing personnel on October 11, 2019 at 3:00 p.m. confirmed no documentation of the highest level of education for testing personnel number one. Testing personnel number one performs patient testing for complete blood count and urine microscopics since 2018.
D6072	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(3) Each individual performing moderate complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed. This STANDARD is not met as evidenced by: Based on review of the laboratory procedure manual, the laboratory's quality control (QC) records and interview with the lead testing personnel, testing personnel number one failed to follow the policy for entry of quality control limits resulting in the use of incorrect limits for lot numbers 068100, 078100, and 088100 for complete blood count (CBC) in 2019. The findings include: 1) Review of the laboratory CBC procedure manual revealed that QC values for CBC are to be entered by more than one person to prevent errors in QC limit entry. 2) Review of the QC assay sheet for lot numbers 068100, 078100, and 088100 revealed entry of QC limits by testing personnel number one on 08.21.2019. There was no second person initials on the QC assay sheet verifying the ranges were correct. 3) Review of the QC package insert and limits in use for lot numbers 068100, 078100, and 088100 revealed the following: Lot 068100 White blood cell (WBC) correct range= 4.3 +/- 0.5 th/uL, range in use = 4.2 +/- 0.5 th/uL Red blood cell (RBC) correct range = 2.38+/- 0.25 mil/uL, range in use = 2.36 +/- 0.25 mil/uL Hemoglobin correct range = 6.6 +/- 0.7 gm/dL, range in use = 6.4 +/- 0.7 gm/dL Hematocrit range = 18.4 +/- 2.7 %, range in use = 18.2 +/- 2.7 % Lot 078100 RBC correct range = 4.21 +/- 0.25 mil/uL, range in use = 4.15 +/- 0.25 mil /uL Hemoglobin correct range = 12.6 +/- 0.9 mg/dL, range in use = 12.4 +/- 0.9 mg /dL Hematocrit correct range = 35.7 +/- 3.0 %, range in use = 35.2 +/- 3.0 % Lot 088100 WBC correct range = 18.4 +/- 1.2 th/uL, range in use = 18.5 +/- 1.2 th/uL RBC correct range = 5.37 +/- 0.3 mil/uL, range in use = 5.30 +/- 0.3 mil/uL Hemoglobin range = 17.5 +/- 0.9 gm/dL, range in use = 17.3 +/- 0.9 gm/dL Hematocrit correct range = 50.4 +/- 4.0 %, range in use = 49.8 +/- 4.0 % Platelet correct range = 389 +/- 60 th/uL, range in use = 385 +/- 60 th/uL 4) Interview with the lead testing personnel on October 11, 2019 at 3:00 p.m. confirmed testing personnel number one failed to follow the laboratory's quality control policy for entry of QC limits resulting in the use of incorrect QC limits for lot numbers 068100, 078100, 088100 from 08.21.19 to 10.11.19, with patient testing performed.