

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2148957	(X3) Date Survey Completed 04/18/2019
Name of Provider or Supplier Kids Clinic	Street Address, City, State 119 Stephen J White Memorial Blvd, Talladega, AL	
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on initial tour observations, a review of installation records, a review of the operators' guidelines for the Reichert Unistat Bilirubinometer, a lack of documentation of specification verifications for the Bilirubinometer (Chemistry testing) and Emerald Cell-Dyn (Hematology), and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure the instruments performed, according to the manufacturers' claims for accuracy, precision and analytical measurable range, prior to beginning patient testing. The findings include: 1. During the initial tour of the laboratory, on April 18, 2019, TP #1 stated the laboratory performed CBCs (Complete Blood Counts) on the Emerald Cell-Dyn and Bilirubins on the Reichert Bilirubinometer. TP #1 also stated the laboratory began patient testing on February 1, 2019. 2. A review of the CLIA manual revealed the Emerald Cell-Dyn was installed in February 2019, with a calibration being performed on February 6, 2019. The Bilirubinometer was installed on January 7, 2019, with documented calibration (only one manufacturer's glass cuvette used) and one high control cuvette. 3. On April 18, 2019 at 10:40 AM, the surveyor inquired about the installation and validation studies for the Cell-Dyn. TP #1 stated she performed a calibration and ran quality controls (QC), which she was instructed to do by the individual who sold the laboratory the instrument. When asked about the purchase of</p>

the instrument, TP #1 explained the Cell-Dyn had been purchased from on-line, and identified the company as "Beke Diagnostics." TP #1 further explained the company had not provided any validation studies to prove accuracy, precision or reportable range, other than a certificate (see paragraph 4). During the interview at 10:40 AM, when asked about the installation and validation of the Bilirubinometer, TP #1 stated she had performed the manufacturer recommended calibration only. At 11:03 AM, the surveyor asked for clarification of the initial studies performed on the Bilirubinometer. TP #1 explained she only used the calibration cuvette, supplied by the manufacturer and the high control cuvette supplied by the manufacturer, as well. No calibration verification had been performed. 4. Further review of the records revealed a "Certificate of Quality Assurance" from "BEKU DIAGNOSTICS, INC." for the Cell-Dyn Emerald, which indicated the following: "It is hereby certified that the following Cell-Dyn Emerald analyzer, with serial No. 033610-001360 has been assembled in compliance with the requirements and specifications listed by the Original Equipment Manufacturer. Inspections records, quality evidence and other objective information are on file at the point of assembly." This certificate was dated January 22, 2019, and was not signed by the Laboratory Director. An "INSTRUMENT VERIFICATION/PREVENTATIVE MAINTENANCE" record for the Cell Dyn Emerald, with the same serial number, from the same company, and dated 01/15/2019 included the following check-marked categories: "1. ANALYZER; a. Lubricate the Pistons. b. Replace all defective / worn parts. c. Check, clean and adjust sampler assembly. d. Check Pressure Levels. e. Clean backwash system. f. Bleach RBC / WBC apertures and electrodes. g. Replace O-rings. l. Verify syringes. 2. GAIN ADJUSTMENT VERIFICATION 3. QUALITY CONTROL..." 5. A review of the manufacturer's guidelines for the Reichert Unistat Bilirubinometer, page 14, revealed the following: "6.4 Calibration Verification Two assayed glass cuvettes are provided with the REICHERT UNISTAT Bilirubinometer: ...Calibration Cuvette ... High-Level Check Cuvette... glass cuvettes may be used to check the bilirubinometer at the mid and high points... A sample cuvette (Reichert cat. no. 13102140) filled with distilled water may be used to check zero. ...Low-Level Check Cuvette (assay value approximately 12 mg/dL (205 umol/L)) may be purchased separately."

D5447

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory's CLIA manual (with policies and procedures), a review of Chemistry Quality Control (QC) records, a review of the manufacturer's guidelines for the Reichert UNISTAT Bilirubinometer, a review of the patient test logs, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to perform at least two levels of quality control each day of patient testing for Bilirubin, in the absence of an IQCP (Individualized Quality Control Plan). This affected at least twenty-seven patients, who had Bilirubin testing from February - April 15, 2019. The findings include: 1. A review of the CLIA manual revealed the Bilirubinometer was installed on January 7, 2019, with a documented calibration (only one manufacturer's glass cuvette used) and one high control cuvette. 2. A review

of QC records for Bilirubin testing revealed only one level (high) of quality control had been run on the instrument on the day of installation, January 7, 2019; although patient testing occurred on multiple days in February, March and April. 3. The patient test logs indicated five patients were tested in February; nine patients in March and thirteen patients in April (from the third to the fifteenth day). 4. In an interview on 4/18/2019 at 11:20 AM, the surveyor discussed the requirement of quality control testing for Chemistry (at least two levels of external quality control each day of patient testing, unless an IQCP is developed to reduce the frequency of testing the QC). TP #1 stated the laboratory did not establish an IQCP. 5. A review of the manufacturer's guidelines for the Reichert Unistat Bilirubinometer, page 14, revealed the following: "7.1 Use of Commercial Serum Controls Analysis of at least a normal and abnormal level of a commercial serum control, assayed for total bilirubin, is recommended for checking performance of the Reichert Unistat Bilirubinometer. 7.2 Quality Control Frequency Quality control procedures should be performed before and after each sample run in response to questionable patient results and/or as mandated by local regulations."

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 initial tour observations, a review of installation records, a review of the operators' guidelines for the Reichert Unistat Bilirubinometer, a lack of documentation of specification verifications for the Bilirubinometer (Chemistry testing) and Emerald Cell-Dyn (Hematology), a review of quality control and personnel records, a review of patient test logs, and interviews with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director failed to fulfill the director's responsibilities as noted in the following paragraphs: The findings include: 1. The Laboratory Director failed to ensure the position of Technical Consultant was filled with a qualified individual (must meet qualifications at 493.1411) to provide technical oversight in accordance with the CLIA (Clinical Laboratory Improvement Amendments) regulations at 493.1413. Refer to D6028, D6033 and D6034. 2. The Laboratory Director failed to ensure testing personnel analyzed at least two levels of quality control each day of patient testing for Bilirubin, in the absence of an IQCP (Individualized Quality Control Plan). This affected at least twenty-seven patients, who had Bilirubin testing from February - April 15, 2019. Refer to D6020 and D5447. 3. The Laboratory Director failed to ensure the instruments (Cell-Dyn Emerald and Reichert Unistat Bilirubinometer) performed, according to the manufacturers' claims for accuracy, precision and analytical measurable range, prior to beginning patient testing in February 2019. Refer also to D6013 and D5421.

D6013

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(ii)

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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;

This STANDARD is not met as evidenced by:

Based on initial tour observations, a review of installation records, a review of the operators' guidelines for the Reichert Unistat Bilirubinometer, a lack of documentation of specification verifications for the Bilirubinometer (Chemistry testing) and Emerald Cell-Dyn (Hematology), and an interview with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director failed to ensure the instruments performed, according to the manufacturers' claims for accuracy, precision and analytical measurable range, prior to beginning patient testing. The findings include: 1. During the initial tour of the laboratory, on April 18, 2019, TP #1 stated the laboratory performed CBCs (Complete Blood Counts) on the Emerald Cell-Dyn and Bilirubins on the Reichert Bilirubinometer. TP #1 also stated the laboratory began patient testing on February 1, 2019. 2. A review of the CLIA manual revealed the Emerald Cell-Dyn was installed in February 2019, with a calibration being performed on February 6, 2019. The Bilirubinometer was installed on January 7, 2019, with documented calibration (only one manufacturer's glass cuvette used) and one high control cuvette. 3. On April 18, 2019 at 10:40 AM, the surveyor inquired about the installation and validation studies for the Cell-Dyn. TP #1 stated she performed a calibration and ran quality controls (QC), which she was instructed to do by the individual who sold the laboratory the instrument. When asked about the purchase of the instrument, TP #1 explained the Cell-Dyn had been purchased from on-line, and identified the company as "Beke Diagnostics." TP #1 further explained the company had not provided any validation studies to prove accuracy, precision or reportable range, other than a certificate (see paragraph 4). During the interview at 10:40 AM, when asked about the installation and validation of the Bilirubinometer, TP #1 stated she had performed the manufacturer recommended calibration only. At 11:03 AM, the surveyor asked for clarification of the initial studies performed on the Bilirubinometer. TP #1 explained she only used the calibration cuvette, supplied by the manufacturer and the high control cuvette supplied by the manufacturer, as well. No calibration verification had been performed. 4. Further review of the records revealed a "Certificate of Quality Assurance" from "BEKU DIAGNOSTICS, INC." for the Cell-Dyn Emerald, which indicated the following: "It is hereby certified that the following Cell-Dyn Emerald analyzer, with serial No. 033610-001360 has been assembled in compliance with the requirements and specifications listed by the Original Equipment Manufacturer. Inspections records, quality evidence and other objective information are on file at the point of assembly." This certificate was dated January 22, 2019, and was not signed by the Laboratory Director. An "INSTRUMENT VERIFICATION/PREVENTATIVE MAINTENANCE" record for the Cell Dyn Emerald, with the same serial number, from the same company, and dated 01/15/2019 included the following check-marked categories: "1. ANALYZER; a. Lubricate the Pistons. b. Replace all defective / worn parts. c. Check, clean and adjust sampler assembly. d. Check Pressure Levels. e. Clean backwash system. f. Bleach RBC / WBC apertures and electrodes. g. Replace O-rings. l. Verify syringes. 2. GAIN ADJUSTMENT VERIFICATION 3. QUALITY CONTROL..." 5. A review of the manufacturer's guidelines for the Reichert Unistat Bilirubinometer, page 14, revealed the following: "6.4 Calibration Verification Two assayed glass cuvettes are provided with the REICHERT UNISTAT Bilirubinometer: ...Calibration Cuvette ... High-Level Check Cuvette... glass cuvettes may be used to check the bilirubinometer at the mid and high points... A sample cuvette (Reichert cat. no. 13102140) filled with

distilled water may be used to check zero. ...Low-Level Check Cuvette (assay value approximately 12 mg/dL (205 umol/L)) may be purchased separately." 6. See also D5421.

D6020

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 the quality control program is established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's CLIA manual (with policies and procedures), a review of Chemistry Quality Control (QC) records, a review of the manufacturer's guidelines for the Reichert UNISTAT Bilirubinometer, a review of the patient test logs, and an interview with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director failed to ensure testing personnel analyzed at least two levels of quality control each day of patient testing for Bilirubin, in the absence of an IQCP (Individualized Quality Control Plan). This affected at least twenty-seven patients, who had Bilirubin testing from February - April 15, 2019. The findings include: 1. A review of the CLIA manual revealed the Bilirubinometer was installed on January 7, 2019, with a documented calibration (only one manufacturer's glass cuvette used) and one high control cuvette. 2. A review of QC records for Bilirubin testing revealed only one level (high) of quality control had been run on the instrument on the day of installation, January 7, 2019; although patient testing occurred on multiple days in February, March and April. 3. The patient test logs indicated five patients were tested in February; nine patients in March and thirteen patients in April (from the third to the fifteenth day). 4. In an interview on 4/18/2019 at 11:20 AM, the surveyor discussed the requirement of quality control testing for Chemistry (at least two levels of external quality control each day of patient testing, unless an IQCP is developed to reduce the frequency of testing the QC). TP #1 stated the laboratory did not establish an IQCP. 5. A review of the manufacturer's guidelines for the Reichert Unistat Bilirubinometer, page 14, revealed the following: "7.1 Use of Commercial Serum Controls Analysis of at least a normal and abnormal level of a commercial serum control, assayed for total bilirubin, is recommended for checking performance of the Reichert Unistat Bilirubinometer. 7.2 Quality Control Frequency Quality control procedures should be performed before and after each sample run in response to questionable patient results and/or as mandated by local regulations." 6. See also D5447.

D6028

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(10)

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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in

accordance with the personnel responsibilities described in this subpart;

This STANDARD is not met as evidenced by:

Based on a review of the Laboratory Personnel Report (CMS form #209), a review of the personnel records, and an interview with Testing Personnel (TP) #1, the surveyor determined the Laboratory Director failed to ensure the position of Technical Consultant was filled with a qualified individual (must meet qualifications at 493.1411) to provide technical oversight in accordance with the CLIA (Clinical Laboratory Improvement Amendments) regulations at 493.1413. The findings include: 1. Refer to D6033 and D6034.

D6033

TECHNICAL CONSULTANT-MODERATE COMPLEXITY

CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on a review of the Laboratory Personnel Report (CMS form #209), a review of the personnel records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure the position of Technical Consultant was filled with a qualified individual (must meet qualifications at 493.1411) to provide technical oversight in accordance with the CLIA (Clinical Laboratory Improvement Amendments) regulations at 493.1413. The findings include: 1. A review of the CMS form #209 revealed the laboratory staff had listed the Laboratory Director as the Technical Consultant. 2. The personnel file of the Laboratory Director failed to include supporting documentation of qualifications as a technical consultant, which is required for a laboratory, performing moderate complexity testing. 3. At 11:15 AM on 4/18/2019, the surveyor discussed the credentials and qualifications of the technical consultant with TP #1. TP #1 confirmed the qualifications were not on file at the laboratory; but may be possible to obtain. The surveyor asked the testing personnel to fax or email the qualifications by 12:00 Noon on Friday, April 19. Nothing was received by the State Agency from the laboratory by 3:00 PM on April 29, 2019.

D6034

TECHNICAL CONSULTANT QUALIFICATIONS

CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based on a review of the Laboratory Personnel Report (CMS form #209), a review of the personnel records, and an interview with Testing Personnel (TP) #1, the surveyor determined the laboratory failed to ensure the position of Technical Consultant was filled with a qualified individual (must meet qualifications at 493.1411) to provide

technical oversight in accordance with the CLIA (Clinical Laboratory Improvement Amendments) regulations at 493.1413. The findings include: 1. Refer to citation D6033, 493.1409.