

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 15D2064749	(X3) Date Survey Completed 02/11/2019
Name of Provider or Supplier Sip Peds Bedford	Street Address, City, State 1614 25th St, Bedford, IN	
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	<p>493.3 Applicability (a) Basic rule. Except as specified in paragraph (b) of this section, a laboratory will be cited as out of compliance with section 353 of the Public Health Service Act unless it- (1) Has a current, unrevoked or unsuspended certificate of waiver, registration certificate, certificate of compliance, certificate for PPM procedures, or certificate of accreditation issued by HHS applicable to the category of examinations or procedures performed by the laboratory; or (2) Is CLIA-exempt. (b) Exception. These rules do not apply to components or functions of - (1) Any facility or component of a facility that only performs testing for forensic purposes; (2) Research laboratories that test human specimens but do not report patient specific results for the diagnosis, prevention or treatment of any disease or impairment of, or the assessment of the health of individual patients; or (3) Laboratories certified by the Substance Abuse and Mental Health Services Administration (SAMHSA), in which drug testing is performed which meets SAMHSA guidelines and regulations. However, all other testing conducted by a SAMHSA- certified laboratory is subject to this rule. (c) Federal laboratories. Laboratories under the jurisdiction of an agency of the Federal Government are subject to the rules of this part, except that the Secretary may modify the application of such requirements as appropriate. This Basic Rule is not met as evidenced by: Based on record review of the Casper Report 0153D, Casper Report 0155D, the CLIA 116 Aspen Web database, observation during an unannounced complaint survey, and interview with the technical consultant, the laboratory failed to have a current certificate of registration, certificate of compliance or certificate of accreditation to perform waived and moderately complex hematology testing for complete blood cell (CBC) since August 27, 2015. Findings include: 1. Review of the Casper Report 0153D, Casper Report 0155D, and the CLIA 116 Aspen Web database revealed the following: a. Casper Report 0153D, "Unsatisfactory (failed) and Unsuccessful (2 of 3) PT Report" , revealed the laboratory had unsatisfactory and/or unsuccessful proficiency testing results for Virology testing event 1 2018. b. Review of the Casper Report 0155D, "Individual Laboratory Profile", revealed the laboratory had unsatisfactory proficiency testing results for hemoglobin (Hgb) event 3 of 2017 and Virology for event 1 of 2018. Additional testing listed for proficiency testing included white blood count differential (WBC), red blood cell</p>

(RBC), Hematocrit (Hct), hemoglobin (Hgb), white blood count, and platelets (Plt). c. CLIA 116 Aspen Web database revealed that the laboratory's CLIA certificate expired on August 26, 2015 and was terminated on August 27, 2015 for nonpayment of fees. 2. On February 11, 2019 during an unannounced complaint survey, the laboratory was performing waived (Virology and Toxicology), and moderately complex hematology (WBC, RBC, Hct, Hgb, and Plt) testing. 3. Record review for 5 (MR#1 - #5) patient charts reviewed (10/10/18, 11/08/18, 12/13/18, 1/22/19, and 2/08/19) revealed the laboratory performing and reporting moderately complex hematology (WBC, RBC, Hct, Hgb, and Plt) testing without benefit of a valid CLIA certificate. 4. In interview on 2/11/19 at 10:30 a.m., testing person (TP) #8 (Technical Consultant) stated the office was unaware that their CLIA certificate had expired and the laboratory has been performing patient testing in hematology and waived virology and toxicology without certification. 5. The annual test volume for hematology was 1872.

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 lack of documentation and staff interview, the laboratory director had not established or maintained a quality assessment (QA) program to assess the quality of laboratory services performed for one of one non-waived specialty (Hematology). Finding(s) include: 1. On 2/11/19 at 12:25 p.m., upon request for QA reviews performed by the laboratory, TP#8 (Technical Consultant) stated none was available. 2. On 2/11/19 at 12:30 p.m., upon request for a QA policy, TP#8 (Technical Consultant) stated none was available. 3. On 2/11/19 at 12:35 p.m., TP#8 (Technical Consultant) confirmed no policy/procedure for a QA program or documentation of QA meetings, available for review.

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 record reviews and staff interview, the technical consultant failed to document six month or annual competency for two of three testing persons (TP#6 and TP#7) responsible for Moderate complexity testing from 2015 -2018. Finding(s) included: 1. The policy, "Competency Assessment and Annual Compulsory Requirements", PolicyStat ID: 3703608, reviewed 7/2015, read: "Semi-annual (6 month) competency will be performed the first year of employment on all individuals responsible for any pre-analytical, analytical or post-analytical duties and then annually thereafter, regardless of seniority or experience." 2. Review of personnel

files for TP#'s 6 & 7 indicated that no six month or annual competency documentation was available, hire dates on 7/13/15 and 7/18/16. 3. In interview on 2/11/19 at 11:20 a. m., TP#8 (Technical Consultant) acknowledged the two above-listed testing personnel had no competency documentation.