

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0111054	(X3) Date Survey Completed 07/17/2018
Name of Provider or Supplier Pediatric Professional Associates Pa	Street Address, City, State 330 Ratzer Rd, Suite D20, Wayne, NJ	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Liquichek Pediatric Control Manufacture Package Insert (MPI) and interview with the Technical Supervisor (TS), the laboratory failed to follow MPI directions for storage and stability for Quality Control (QC) material from 8/18/16 to the date of survey. The findings include: 1.The MPI stated "Once thawed, do not refreeze this product. This product is shipped under frozen conditions", but the laboratory thawed and aliquoted the QC material into 14 parts, then refroze the QC material. 2. Approximately 72 patients affected for Bilirubin tests. 3. The TS confirmed on 7/17/18 at 10:00 am that MPI was not followed.</p>
D5469	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be</p>

established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Quality Control (QC) records and interview with the Technical Supervisor (TS) the laboratory failed to verify that the assayed QC materials were within the acceptable ranges before they were put into use for Bilirubin performed on the Unistat Bilirubinometer analyzer from 8/18/16 to the date of survey. The TS confirmed on 7/17/18 at 10:30 am that the laboratory did not verify QC materials for Bilirubin performed on Unistat Bilirubinometer analyzer.

D5477

CONTROL PROCEDURES

CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to check QC on each batch of Urine Culture Media for the Ability to select or inhibit specific organisms from 8/18/16 to the date of the survey. The TS confirmed on 7/17/18 at 11:00 am that the laboratory did not perform the above-mentioned QC check.