

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 46D0523874	(X3) Date Survey Completed 01/17/2018
Name of Provider or Supplier Tosh	Street Address, City, State 5848 S Fashion Blvd, Murray, UT	
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 instrument test system verification record review and interview with staff, the laboratory failed to demonstrate it could obtain the manufacturer's specifications for accuracy, precision, and reportable range for 3 of 5 Istat analyzers used for testing Beta-Human Chorionic Gonadotropin (BhCG) using the Istat BhCG cartridge. The laboratory began testing with the BhCG cartridge on 11/16/2016. Findings include: 1. The laboratory has 5 Istat analyzers (serial numbers 331506, 363711,363153,359030,33200) used for patient testing. 2. BhCG verification records lack documentation of verification studies for Istat analyzers 331506, 363711, and 33200. 3. The technical consultant stated during the survey on 01/17/2018 method verification studies were not performed on each analyzer but was performed using a "representative" number of analyzers. The quality assurance officer stated in an email on 01/24/2018, "...it is possible for any of the cartridges to be done on any of the Istats".</p>
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the</p>

laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:

Based on calibration verification record review, lack of documentation, and interview with staff, the laboratory failed to verify calibration at least every 6 months in 2017 on 3 of 5 Istat analyzers with 4 Istat cartridges (Chem 8+, CG4, BhCG, Tropl), and failed to verify calibration with the EC4+ cartridge. Findings include: 1. The laboratory has 5 Istat analyzers (serial numbers 331506, 363711, 363153, 359030, 33200) used for testing with the Chem 8+, CG4, BhCG, Tropl, and EC4+ cartridges which require calibration verification. 2. Calibration verification records in 2017 document verification studies performed on 05/25/2017 using the: Tropl cartridge on Istats 331506 and 363153; Chem 8+ cartridge on 331506 and 363153; CG4 cartridge on 331506 and 363153; and the BhCG cartridge on 359030 and 332007. 3. Calibration verification records on 11/16/2017 document verification studies using the: Tropl cartridge on Istats 331506 and 332007; Chem 8+ cartridge on 331506 and 332007; CG4 cartridge on 331506 and 332007; and the BhCG cartridge on 331506 and 332007. 4. The laboratory lacked documentation of calibration verification of the EC4+ cartridge in 2017. 5. Calibration verification is required per test system. 6. The technical consultant stated during the survey on 01/17/2018 the laboratory allows capillary samples (non-waived) to be tested with the Chem 8+ and EC4+ cartridges, and instead of calibration verification performed on each analyzer, verification testing was performed using a "representative" number of analyzers. The quality assurance officer stated in an email on 01/24/2018, "...it is possible for any of the cartridges to be run on any of the Istats".

D5463

CONTROL PROCEDURES
CFR(s): 493.1256(d)(7)(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--
Over time, rotate control material testing among all operators who perform the test.
(g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on laboratory personnel report review, quality control (QC) result review, and interview with staff, the laboratory failed to rotate control material testing among the operators who perform testing for 6 of 6 test cartridges used on the Istat analyzer for 6 QC records reviewed from 12/29/2015-08/17/2017. Findings include: 1. The laboratory personnel report list 30 testing personnel performing non-waived testing on the Istat analyzer. 2. The laboratory performs nonwaived testing using 6 Istat cartridges: CG4, Chem 8+, EC4+, PT/INR, BhCG, and Tropl. 3. Cartridge QC records reviewed for Tropl lot 102R15242921 tested on 03/07/2016, PT/INR lot 334B15293117 tested on 12/29/2015, Chem 8+ lot 218H16242017 tested on 10/20/2016, Chem 8+ lot 229H16171017 tested on 09/22/2016, EC4+ lot 222K16277026 tested on 11/16/2016 and Chem 8+ lot 229H17170017 tested on 08/17/2017 document testing performed by the technical consultant. 4. The technical consultant stated on 01/17/2018 at approximately 11:00 am, she performed all of the cartridge QC testing and testing was not rotated among the operators.