

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2120433	(X3) Date Survey Completed 01/25/2018
Name of Provider or Supplier Healthcare Express-Choctaw	Street Address, City, State 14321 Ne 23rd St, Choctaw, OK	
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	The findings were reviewed with the technical consultant, director of laboratory operations, and the assistant to the director of laboratory operations at the conclusion of the survey.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the technical consultant and director of laboratory operations, the laboratory failed to perform maintenance procedures as required by the manufacturer. Findings include: (1) At the beginning of the survey, the director of laboratory operations stated to the surveyor the laboratory began using the Sysmex XP-300 analyzer to perform CBC (Complete Blood Count) testing on 12/05/16; (2) The surveyor reviewed the manufacturer's maintenance instructions for the analyzer which were: (a) Weekly - Clean SRV Tray (b) Quarterly - Clean Sample Rotor Valve (3) Maintenance records were then reviewed by the surveyor for 12 months (January through December 2017) with the following identified: (a) The weekly maintenance had not been documented as performed between: (i) 01/23/17 and 02/06/17 (ii) 02/20/17 and 03/06/17 (iii) 03/06/17 and 03/20/17 (iv) 03/27/17 and 04/10/17 (v) 05/22/17 and 06/05/17 (vi) 06/19/17 and 07/03/17 (vii) 07/24/17 and 08/07/17 (viii) 09/18/17 and 10/01/17 (ix) 10/23/17 and 11/06/17 (x) 11/06/17 and 11/20/17 (b) The quarterly maintenance had not been documented as performed between: (i) 03/07/17 and 09/12/17 (4) The surveyor reviewed the records with the technical consultant and director of laboratory operations. Both stated there was no evidence the above maintenance had been performed as required.</p>

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(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-- 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 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 a review of records and interview with the technical consultant and director of laboratory operations, the laboratory failed to verify the stated value of control materials before they were put into use. Findings include: (1) At the beginning of the survey, the director of laboratory operations stated the following to the surveyor: (a) The laboratory began using the Sysmex XP-300 analyzer to perform CBC (Complete Blood Count) testing on 12/05/16; (b) Three levels of Sysmex EightCheck-3WP control materials were analyzed each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of quality control results. (2) Later during the survey, the surveyor reviewed records for 12 control lot numbers. There was no evidence the provided ranges were verified before the lot numbers were put into use for 12 of 12 lot numbers as follows: (a) Low control lot #70880712, Normal control lot #70880711, and High control lot #70880712 put into use on 04/13/17 and used through 07/30/17; (b) Low control lot #71720710, Normal control lot #71720711, and High control lot #71720712 put into use on 07/31/17 and used through 09/26/17; (c) Low control lot #72560710, Normal control lot #72560711, and High control lot #72560712 put into use on 09/27/17 and used through 12/19/17; (d) Low control lot #73400710, Normal control lot #73400711, and High control lot #73400712 put into use on 12/20/17 and was currently in use during the survey. (3) The findings were reviewed with the technical consultant and the director of laboratory operations. Both stated the manufacturer's ranges had not been verified before the above lot numbers had been put into use.