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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 17D0453069 | (X3) Date Survey Completed 04/03/2018 |
| Name of Provider or Supplier Decatur Health System Inc | Street Address, City, State 810 W Columbia St, Oberlin, KS | |
| 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 |
|---------------------------|---|
| D5215 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: A review of proficiency testing records from American Proficiency Institute (API) (a year consists of three testing events) and interview with laboratory Supervisor revealed the laboratory failed to verify the accuracy of analytes for which the proficiency testing program does not obtain the agreement required for scoring. Findings were as follows: a. Proficiency testing records form API for the third event of 2016, revealed that the proficiency testing program failed to obtain the agreement required for scoring the Free Thyroxin CHG--13 . : At the time of survey (04/03 /2018), there was no evidence of verification activities of accuracy by self grade (comparison to the published expected results) for any of these analytes available for review. An interview with the General Supervisor from the CMS form 209 on 04/03 /2018, at 10:20 hrs confirmed that no verification of accuracy.</p> |
| D5413 | <p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.</p> |

(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

A review of Temperature and humidity logs and interview with staff revealed the laboratory failed the humidity for the laboratory as the Tosoh AIA-360 Endocrinology analyzer requires. Findings were as follows: a. Based upon review of manufacture's operators guide the laboratory failed the humidity 40% to 80% . The laboratory failed to define the acceptable humidity range according to the manufacture's range, November 2017 through January 2018 b. At the time of the survey 04/03/2018 the laboratory failed to produce corrective action documentation of humidity, This was confirmed by the General Supervisor from the CMS 209 form on 04/03/2018 at 1400 hours.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:

Based upon direct observation during a tour of the laboratory, review of manufacturer's reagent labels and staff interview, the laboratory failed to ensure that reagents in use were not expired. Findings were: a. During a tour of the lab the surveyor observed Nerl Blood Bank Saline was placed in use 12/05/2017 manufacture states use within 30 day lot # 157788 observation was made on 04/03/2018 which made the saline expired 2 months b. The above finding was confirmed by interview with the General Supervisor on 04/03/2018 at 1430 hours in the laboratory.