

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D2047960	(X3) Date Survey Completed 05/16/2018
Name of Provider or Supplier G I Of Norman, Llc	Street Address, City, State 1125 N Porter, Suite 301, Norman, 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 general supervisor #2/testing person #1 at the conclusion of the survey.
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the policy and procedure manual and interview with general supervisor #2/testing person #1, the laboratory failed to follow written procedures for the Grossing Proficiency Assessment policy. Findings include: (1) At the beginning of the survey, general supervisor #2/testing person #1 stated to the surveyor grossing (number of pieces and measurement) was performed on gastrointestinal specimens; (2) Later during the survey, the surveyor reviewed the written procedure titled, "Grossing Proficiency Assessment" which stated, (a) "All histotechnicians will be evaluated on a semi-annual basis. Evaluations will be performed by the Technical Supervisor or designee." (3) The surveyor review records between December 2016 through April 2018 for testing person #1. There was no documentation the semi-annual evaluations had been performed as required by the policy; (4) The surveyor reviewed the findings with general supervisor #2/testing person #1 who stated that the procedure had not been followed as indicated above.</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</p>

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. (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:
Based on a review of records, manufacturer's instructions, observation, and interview with general supervisor #2/testing person #1, the laboratory failed to ensure the ensure humidity readings were within the manufacturer's storage requirements. Findings include: (1) At the beginning of the survey, general supervisor #2/testing person #1 stated the following to the surveyor: (a) The Leica EG1150H - Paraffin Embedding Station was used in the preparation of gastrointestinal specimens. (2) The surveyor reviewed the manufacturer's storage instructions for the above instrument. The manufacturer required a relative air humidity of a maximum of 60%; (3) The surveyor reviewed January 2018 through April 2018 temperature records, which did not include a humidity range; (4) The surveyor reviewed the findings with general supervisor#2 /testing person #1, who stated the humidity had not been taken for the above review period.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on a review of records and interview with general supervisor #2/testing person #1, the laboratory director failed to ensure a testing person had the appropriate training for performing grossing for gastrointestinal specimen. Findings include: (1) At the beginning of the survey, the surveyor reviewed personnel records for testing person #1 who had been hired to perform grossing (number of pieces and measurement) since the recertification survey performed on 04/07/16. There was no documented training for testing person #1 as follows: (a) Testing Person #1, hired on 12/12/16 to perform testing. (2) The surveyor reviewed the records with general supervisor #2/testing person #1 who stated there was no documentation to prove the above person had been trained to perform grossing on gastrointestinal specimens.