Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D2000400	08/10/2021
Name of Provider or Supplier	**Street Address, City, State**	
Diagnostic Pathology Services, Inc Integris Grove	1001 East 18th Street, Grove, 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 recertification survey was performed on 08/10/2021. The findings were reviewed with the quality assessment manager at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on a review of the laboratory monitoring logs and interview with the quality assessment manager, the laboratory failed to follow written procedures for the maintenance of the cryostat for 2 of 9 days. Findings include: (1) On 08/10/2021 at 09: 25 am, the quality assessment manager stated the laboratory performed frozen sections for microscopic interpretations of histology specimens that had been stained with H&E (Hematoxylin & Eosin) stain or toluidine blue stain; (2) The surveyor reviewed cryostat maintenance logs from January 2021 through June 2021, titled "CRYOSTAT TEMPERATURE MONITORING LOG" which stated the following: (a) CMD = "DAILY/WEEKLY MAINTENANCE (CMD is performed on day of use and includes the following: clean the instrument, apply a drop of oil to the plastic coupling and the micrometer and lubricate the specimen cylinder).". (3) The surveyor then compared 9 days of patient testing to the cryostat temperature maintenance log and identified the CMD procedure had not been documented as performed for the following days of patient testing: (a) 05/27/2021 (b) 06/03/2021 (4) The surveyor reviewed the findings with the quality assessment manager, who stated on 08/10/2021 at 10:50 am the CMD procedure had not been documented on 05/27/2021 and 06/03 /2021 as indicated above.

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 on observation and interview with the quality assessment manager, the laboratory failed to ensure that staining procedures were not performed with expired staining materials. Findings include: (1) On 08/10/2021 at 09:25 am, the quality assessment manager stated the laboratory performed microscopic interpretations of histology specimens that had been stained with H&E (Hematoxylin & Eosin) stain; (2) On 08/10/2021 at 09:40 am, the surveyor observed one bottle of FisherChem Histological Grade Reagent Alcohol (lot# 179328) had a manufacturer's expiration date of March 2021 available for use; (3) The surveyor showed the bottle to the quality assessment manager, who stated to the surveyor on 08/10/2021 at 09:50 am, the expired material was available for use.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (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 quality assessment manager, the laboratory failed to document the reactivity of the H&E (Hematoxylin & Eosin) stain each day of testing for 1 of 15 days of patient testing. Findings include: (1) On 08/10 /2021 at 09:25 am, the quality assessment manager stated the laboratory performed microscopic interpretations of histology specimens that had been stained with H&E (Hematoxylin & Eosin) stain; (2) The surveyor reviewed test records for 15 days of patient testing (microscopic interpretations) performed from January 2020 through June 2021. There was no evidence that the reactivity of the stain had been observed for acceptability for the 1 (11/14/2020) of the 15 days; (3) The surveyor reviewed the findings with the quality assessment manager, who stated on 08/10/2021 at 10:35 am the reactivity of the stain was observed for acceptability on each patient slide, but had not been documented on 11/14/2020.