Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D1094125	07/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Gut Pathology Llc	480 Honeysuckle Road, Dothan, AL	

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
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 quality control records (Daily Accuracy of Histology Stain, Slide Labeling and Data Entry logs), a review of the policies and procedures, and an interview with the Laboratory Director (the only testing personnel for Histopathology), the surveyor determined the Laboratory Director (Testing Personnel) failed to ensure the reactions and characteristics (quality) of the pathology slides were documented each day of patient slide interpretations. This affected the survey review period, November 2017 - July 24, 2019. The findings include: 1. A review of the "Daily Accuracy of Histology Stain, Slide Labeling and Data Entry" (quality control) records for 2017, 2018 and 2019, revealed the testing personnel failed to document the reactions and characteristics of the pathology slides for the survey review period of November 2017 - July 2019. The form included columns for slide quality and stain; however the columns were left blank for the time-frame previously mentioned. 2. During an interview on July 29, 2019 at 11:23 AM, the surveyor asked the Laboratory Director if the slide and stain adequacy were monitored for the Histopathology slides. The Laboratory Director stated the accuracy of the slides was documented in the manual with the documents of daily accuracy of Histology. When the surveyor stated she was unable to see this documented, the Laboratory Director reviewed the manual and the logs, and confirmed the missing documentation, stating it appeared she failed to document the accuracy for quite some time. The Laboratory Director further stated she reviewed each slide daily, but failed to document the evaluations. 3. Further

	review of the quality control logs revealed the Laboratory Director (Testing Personnel) did not document the slide/staining accuracy from November 2017 - July 24, 2019. 4. The surveyor inquired of the Laboratory Director the policy for the quality control of the slides. The Laboratory Director stated the policy was in the QA (Quality Assurance) Manual. The Laboratory Director reviewed the policy and stated the slide quality is evaluated daily by the reading pathologist. The policy further indicated the slide quality encompassed embedding, microtomy and staining of slides. .
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of the "Accuracy and Quality of Final Diagnosis Performance Improvement Indicator" records for May 2017 - July 25, 2019, a review of the policy and procedure for pathologist competency, and an interview with the Laboratory Director [Testing Personnel (TP) #1] and TP #2, the surveyor determined the Laboratory Director failed to ensure quality assessments were done to effectively identify any problems in slide peer reviews to assure corrective actions were implemented, if necessary. This affected the month, September 2018. The finding include: 1. A review of the records, titled "Accuracy and Quality of Finial Diagnosis Performance Improvement Indicator" revealed each month at least three cases were sent to an off-site pathologist for review of adequate gross description, adequate stage and grade, and diagnosis agreement or disagreement. A review of these records for September 2018 revealed a list of three cases; however no results or evaluations of the slides were documented. 2. There was no documentation the above peer review was reviewed for completion or discrepancies. 3. At 11:43 AM on 7/29/2019, the surveyor reviewed the policy and procedure, "Pathologist Competency Assessment Policy." The policy indicated the accuracy and quality of the final diagnosis of surgical pathology cases would be assessed at least every six months, with approximately three surgical cases per month being sent to an outside reviewer. 4. During the exit interview on 7/29/2019 at 12:00 PM, the surveyor discussed the survey findings with the Laboratory Director (TP #1) and TP #2. The surveyor reviewed the records with the Laboratory Director, who reviewed the September 2018 record, confirmed no evaluation of the slides had been made be a peer, and stated she was not aware what happened with the cases in September (2018).