Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0938658	02/07/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Laboratory Associates	1108 Ross Clark Circle, 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
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of the stain quality control records, a review of the policy and procedure manual, a review of patient reports, and an interview with the laboratory supervisor, the surveyor determined the laboratory failed to document quality control results for special stains used on 1/20/2017 for three patient cases. This affected one day and potentially three patient reports for the survey period of 2017 through 2018. 1. A review of the laboratory's policy and procedure manual indicated the quality control of the immunohistochemical stains were reviewed on a daily basis. 2. A review of the quality control records (Special Stain Log) revealed the quality control was not documented for the following: a) On 1/20/2017 for Case #S17475 [AFB (Acid Fast Bacilli), Gram, PAS (Periodic Acid Schiff), GMS (Gomori Methenamine-Silver) stains] b) On 1/20/2017 for Case #S17455 (Iron, Trichrome stains) c) Case #S17424 (GMS, PAS, AFB stains) 3. In an interview on 2/07/2019 at 12:20 PM, the laboratory supervisor reviewed the special stain quality control log with the surveyor and confirmed the controls had not been documented on 1/20/2017 for the cases listed in paragraph 2. At this time, the surveyor requested the patient cases (reports) for 1/20 /2017 be pulled for review. 4. A review of the three patient reports revealed of the three reports, the report for Case #S17475 included the following under, Microscopic Description: "Microscopic examination is performed. A PAS, GMS, AFB and gram stain are performed with appropriate tissue controls." The pathologists failed to

	document the reactivity of the quality control for these special stains, performed on 1 /20/2017 for the three cases afore-mentioned. 5. The above noted findings were discussed with Testing Personnel #1, the laboratory supervisor and three hospital administrators, during the exit summation on 2/07/19 at 2:40 PM.
D5667	CYTOLOGY CFR(s): 493.1274(h) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of Cytology (non-gynecological) quality control logs and an interview with the laboratory supervisor, the surveyor determined the laboratory testing personnel (the reviewing pathologists) failed to document quality control for stains performed on Cytology specimens for seven cases (seven days) for the survey review period of 2017 through 2018. The findings include: 1. A review of the Daily Stain QA (Quality Assurance) and Pathologist Workload for Cytology revealed seven days when the quality control of the stain was not documented. The following cases and dates were described as: 12/14/2018, C18-1150; 9/27/17, C17-710, 7/20/17, C17-488, 7/12/17, C17-470, 5/8/17, C17-305, 3/3/17, C17-142, and 4/21/17, C17-267. 2. On 2/07/2019 at 12:20 PM, the surveyor reviewed the logs with the laboratory supervisor. The laboratory supervisor confirmed the quality control had not been documented. When asked about the quality control for the patient slides, the laboratory supervisor explained the quality control as being an "internal quality control," because it is included within the patient specimen (slide). The laboratory supervisor further stated no determinations had been made on how or if any patients had been affected. 3. The above noted findings were discussed with Testing Personnel #1, the laboratory supervisor and three hospital administrators, during the exit summation on 2/07/19 at 2:40 PM.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of the stain quality control records, a review of the policy and procedure manual, a review of patient reports, and an interview with the laboratory supervisor, the surveyor determined the laboratory failed to ensure corrective actions were implemented and documented when special stains, performed in Histopathology, and stains used in Cytology failed quality control on four days in 2017 and 2018. This potentially affected five patient cases. The laboratory further failed to implement and document corrective actions for patients potentially affected by the failure to document the quality control for Histopathology and Cytology stains (See D5601 and D5667). This affected eight days and potentially seven patient cases. The findings include: 1. A review of the quality control records (Special Stain Log) revealed the

	quality control for PAS (Periodic Acid Schiff was not acceptable, as documented by the pathologists for the following: a) On 9/27/17 for Case 17-7061 (documented to replace Schiff) b) On 11/06/17 for Case S17-8127 (documented to replace Schiff) c) On 11/06/17 for Case S17-8107 (documented to replace Schiff) 2. No corrective actions were documented for the above mentioned quality control failures. 3. A review of the Daily Stain QA (Quality Assurance) and Pathologist Workload for Cytology revealed two days when the quality control of the stain was documented as not acceptable: 12/03/18 for Case C18-1099 (6 slides) and 12/04/18 for Case C18-1100 (4 slides). 4. On 2/07/2019 at 12:20 PM, the surveyor reviewed the logs with the laboratory supervisor. The laboratory supervisor confirmed the dates (listed above and noted in D5601 and D5667) when the quality control had not been documented and when the quality control was not acceptable. When asked, the laboratory supervisor stated if a problem was discovered with the stain material (the quality control), the slide processor would redo the stain after changing the necessary reagents. However, the laboratory director confirmed the laboratory had not documented any corrective actions for the quality control failures. Further, the laboratory supervisor stated no determinations had been made on how or if any patients had been affected. 5. The above noted findings were discussed with Testing Personnel #1, the laboratory supervisor and three hospital administrators, during the exit summation on 2/07/19 at 2:40 PM. 6. Also see D5601 and D5667.