Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0609327	07/09/2019
Name of Provider or Supplier	**Street Address, City, State**	
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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
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the systemic nature of laboratory's failure to monitor and document the quality review of the general patient testing procedures as specified in 493.1239 for each specialty and subspecialty of testing performed. The findings include: a. The laboratory failed to have a procedure manual for each test or procedure they perform. See D5403. b. The laboratory failed to document the quality of stain for histopathology stains performed. See D5601. c. The laboratory failed to perform and document the required function checks for the laboratory equipment. See D5429. d. The laboratory failed to perform and document the controls for KOH testing. See D5449. e. The laboratory failed to ensure that the reagents had not expired prior to use. See D5417.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step

	performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on request for procedure manual, record review and interview with staff technician on July 9, 2019, the laboratory failed to have a written procedure manual for all tests, assays, and examinations performed by the laboratory. Findings included: a. Upon request for the laboratory's procedure manual for histopathology testing, potassium hydroxide (KOH) testing, and quality assessment, the laboratory did not have procedures or policies for the testing they perform at the time of the survey. b. The laboratory performs histopathology slide review with differential stains, and KOH tissue exams, and did not have a procedure for the following. (1) Requirements for patient preparation; criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination including detection of inadequately prepared slides, controls, reagents, and other materials used in testing. (3) Control procedures. (4) Corrective actions to take when control results fail to meet the laboratory's criteria for acceptability. (5) The laboratory's system for entering results in the patient record and reporting patient results including , when appropriate the protocol for reporting imminently life threatening results, or panic or alert values. (6) Slide retention criteria. c. The laboratory technician confirmed the lack of a procedure manual by interview on July 9, 2019 at approximately 2:50 pm. d. The laboratory reportedly performs 2500 histopathology slide reviews and 40 KOH patient specimens annually.
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 of the Potassium Hydroxide (KOH) reagent container and interview with the laboratory director and staff technician on July 9, 2019, the laboratory failed to not use reagents when they have exceeded their expiration date, have deteriorated, or are of substandard quality. The findings include: a. Upon review of the KOH reagent bottle in use, the expiration date indicated it had been expired for over a year. b. On the KOH bottle (lot # 1355308C) the manufacturer's label indicated that the bottle had expired on June 20, 2018. c. The laboratory director and the

	laboratory technician confirmed by interview that the laboratory was using expired reagent on July 9, 2019 at approximately 3:25 pm. d. The laboratory reports performing approximately 40 KOH tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory's equipment, and interview with the laboratory director and laboratory technician on July 9, 2019 the laboratory failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. The findings include: a. Upon request for the laboratory's function check service reports, the laboratory had no documentation for the functions checks being performed either for April 19, 2017, the year 2018 or for the year 2019 on date of survey. b. Upon review of the laboratory's three microscopes, the function check tabs on two of the microscopes had expired on April 19, 2018, and the third microscope which was new and had no function check sticker or service reports to verify function checks prior to placing the microscope in use. 955293 (KOH) - Last PM 04/19/2017 470432 (Accuscope) - Last PM 04/19/2017 E-200- (new microscope) - No function checks indicated. c. The laboratory director and laboratory technician confirmed by interview on July 9, 2019 at approximately 3:15 pm, the lack of documentation for service reports and confirmed lack of the current functions checks for the three microscopes.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on interview with the laboratory technician and the laboratory director on July 9, 2019, the laboratory failed to at least once a day patient specimens are assayed or examined, include a negative and positive control material for their Potassium Hydroxide (KOH) testing and failed to document all control procedures performed. The findings include: a. On the day of survey, the laboratory failed to provide documentation of control materials for KOH testing. The laboratory had no documentation of previous controls or KOH testing logs from previous surveys throught the July 9, 2019 survey dates. b. The laboratory director confirmed by interview on July 9, 2019 at approximately 3:25 pm, that the laboratory does not perform controls for the KOH procedures. The laboratory technician confirmed by interview that the laboratory does not document the KOH testing or control procedures performed. c. The laboratory reports performing approximately 40 KOH procedures annually.

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 review of the laboratory's histopathology log and interview with the laboratory technician on July 9, 2019, the laboratory failed for their differential or special stains, provide a control slide of known reactivity stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain was not documented. The findings include: 1. The laboratory sends their specimens to an outside lab to gross and prepare their histopathology slides, and per interview with the laboratory technician they do not receive a control slide back with their patient slides stained for each day. 2. The laboratory histopathology patient log book contains a space for the laboratory director (testing personnel) to indicate the satisfactory or unsatisfactory status of the slides stain quality. a. Upon review of the patient slide review log, the laboratory testing personnel failed to identify the acceptability or unacceptability of the quality of the stain for the slides or the group of slides which had been prepared. b. For the dates 11-12-2018 to 01-04-2019, no quality assessment of the slide staining had been documented. There were 178 patients evaluated during this time period. c. For the dates 01-09-2018 to 01-23-2018, no quality assessment of the slide staining had been documented. There were 62 patients evaluated during this time period. d. For the dates 01-21-2018 to 02-23-2018, no quality assessment of the slide staining had been documented. There were 141 patients evaluated during this time period. 3. The laboratory technician by interview confirmed the lack of stain quality evaluation documentation, and the lack of control slides on July 9, 2019 at approximately 2:15 pm. 4. The laboratory reports performing approximately 2500 histopathology slide reviews annually.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on the number of identified deficiencies on July 9, 2019, and the systemic nature of the failure to monitor and review all patient testing quality control and maintenance records, the laboratory director failed to provide overall management and direction to the laboratory in accordance with 493.1445 of this subpart. The findings include: a. The laboratory director failed to provide a procedure manual to ensure quality testing for each test performed and to ensure that the laboratory maintained documentation of control and maintenance procedures. See D6082.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory histopathology logs, maintenance logs and interview with the laboratory director and staff technician on July 9, 2019, the laboratory director failed to ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. The findings include: a. The laboratory director failed to have an approved procedure manual or quality assessment procedures to ensure that all aspects of the laboratory testing performed provided quality results. See D5200, D5403, D5417, D5429, D5449, D5601.