Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D2161971	12/09/2019
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
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of the final histology slide labeling and interview with the laboratory director/testing personnel, it was determined that the laboratory failed to ensure that the histology laboratory provided adequate and proper patient information on the slide label such as the source of the specimen, the date of specimen collection, and any additional information relevant and necessary for histology testing to ensure accurate and timely testing and reporting of results. The findings included: a. This laboratory sends its biopsy specimen to Path MD, a histology laboratory, to process tissue slides. b. A qualified pathology performed professional component onsite and generate the surgical pathology reports using Window Path, a laboratory information system. c. This laboratory provides biopsy specimens and indicates to Path MD histology laboratory for the following information, including but are not limited to, patient name, source of specimen, date of collection, etc. d. Review of 5 laboratory surgical

	pathology reports; S2019-016970, S2019-016980. S2019-016966, S2019-016026, S2019-013872 along with its corresponding slides. e. Each slide label indicates: slide ID, block ID, H&E (special stain), Patient name, Path MD, and a QR code. f. Path MD, the histology laboratory, failed to provide and indicate the specimen collection date, and specimen source on the slide labels. g. This laboratory and the testing pathologist accept the slides with missing important information such as date of collection, source of specimen necessary for histology test to ensure accurate and timely testing and reporting of results
D5309	TEST REQUEST CFR(s): 493.1241(e) If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately. This STANDARD is not met as evidenced by: Based on review of the laboratory's Surgical Pathology Reports (SPR) and its corresponding slide labels, and interview with the laboratory director/testing personnel, it was determined that the laboratory failed to ensure the accuracy and consistency when transcribing test requisition or authorization information into a record system or a laboratory information system. The findings included: a. Review of 5 laboratory surgical pathology reports; S2019-016970, S2019-016980. S2019-016966, S2019- 016026, S2019-013872 along with its corresponding slide labels. b. Path MD, a histology laboratory, labels the tissue slide with A, B, C or... with A1, B1, C1...to identify different specimen sources when received. c. The SPR under "DIAGNOSIS" does not show consistent descriptions: Example 1: S2019-016980 Slides labeled: A1 and B1 (without any specimen source) SPR Diagnosis A. COLON, RANDOM, BIOPSY B. DESCENDING COLON, POLY, BIOPSY Example 2: S2019-016970 slides labeled: A1 GIEMSA -HP, A1 H&E, and GIEMSA-ctrl SPR Diagnosis STOMACH, POLY, BIOPSY No A or A1 while the diagnosis description was based on the slides; H&E and GIEMSA A1 d. For Example 1: A vs A1; B vs B1; Example 2: No A or no A1 vs A1 H&E, GIEMSA slides are not consistent. e. The laboratory failed to ensure the accuracy and consistency when transcribe test requisition or authorization information into a record system or a laboratory information system.
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 review of the laboratory's pathology policy procedures (PPP), and interview with the laboratory director/testing personnel, it was determined that the laboratory failed to establish, and maintain its own procedure manual. The findings included: a. Review of a cover page of Pathology, Standard Operating Procedure titled with Angie Sadeghi, MD, the name of the laboratory seeking for a CLIA certification. b. Follow that page, contained PATHOLOGY POLICY AND PROCEDURE (PPP) with various "SUBJECT" for this laboratory were titled under "PATH MD" for various "SUBJECT" c. The current laboratory director did not signed and date for each "SUBJECT" section in the laboratory PPP. d. The laboratory must have its own written PPP with its title.
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory's surgical pathology report (SPR) and histological slide labeling, and interview with the laboratory director/testing personnel, it was determined that the laboratory failed to indicate the test report date on SPR. The findings included: a. The laboratory performed histopathology testing and provided the final diagnosis. b. CLIA 42 CFR part 493.1291 (c) requires that the test report must indicate the following: (1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (2) The name and address of the laboratory location where the test was performed. (3) The test report date. (4) The test performed. (5) Specimen source, when appropriate. (6) The test result and, if applicable, the units of measurement or interpretation, or both. (7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. c. Review of 5 laboratory surgical pathology reports; S2019-016970, S2019-016980. S2019-016966, S2019-016026, S2019-013872. d. These reports indicated: Patient name, Submitter(s), Age, Sex, Accession No., Collection Date, Patient phone, and Electronic Signature, (Case signed date). e. The laboratory failed to indicate the report date. f. The date of the test report is the date results were generated as a final report and must not change on copies generated later. g. A case sign date does not indicate the report date.
D5805	TEST REPORT

	CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of the laboratory's surgical pathology report (SPR) and histological slide labeling, and interview with the laboratory director/testing personnel, it was determined that the laboratory failed to indicate the test report date on SPR. The findings included: a. The laboratory performed histopathology testing and provided the final diagnosis. b. CLIA 42 CFR part 493.1291 (c) requires that the test report must indicate the following: (1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (2) The name and address of the laboratory location where the test was performed. (3) The test report date. (4) The test performed. (5) Specimen source, when appropriate. (6) The test result and, if applicable, the units of measurement or interpretation, or both. (7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. c. Review of 5 laboratory surgical pathology reports; S2019-016970, S2019-016980, S2019-016966, S2019-016026, S2019-013872. d. These reports indicated: Patient name, Submitter(s), Age, Sex, Accession No., Collection Date, Patient phone, and Electronic Signature, (Case signed date). e. The laboratory failed to indicate the report date. f. The date of the test report is the date results were generated as a final report and must not change on copies generated later. g. A case sign date does not indicate the report date. h. The current laboratory director is also the qualified testing personnel who signs out the patient Surgical Pathology Report (SPR). i. Discrepancy of the electronic signature of the testing person name and the current laboratory director name shown on the report header were noted; Lydia M Petrovic, M.D. Pathologist vs Lidjia Petrovic, MD. j. Inconsistency of the first name of the current laboratory director shown as Lidija in CMS-209, and Lab 183 vs Lidjia in CMS-116 page 1, and Lab 116 forms were noted.
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 review of the laboratory pathology policy procedures, the patient test result reports, and tissue slide labels, and interview with the laboratory director/testing personnel, it was determined that the laboratory director failed to ensure that the quality assessment programs were established and maintained to assure the quality of laboratory services provided. The findings included: a. The laboratory director performing high complexity testing, such as histopathology, must ensure that testing

	systems developed and selected provide quality laboratory services for all aspects of test performances, which includes pre-analytic, analytic, and post-analytic phases of testing. b. The laboratory received and accepted the tissue slides missing necessary information on the labels to ensure accurate diagnosis (see D-5305). c. The laboratory failed to ensure the accuracy and consistency of the patient and specimen information transcribed and documented in the patient surgical pathology report and its corresponding tissue slide labels and to ensure the final report format in compliance with CLIA post-analytic system (see D-5309, D-5801, & D-5805). d. The laboratory failed to establish its own titled written Pathology Policy Procedure but uses titled other laboratory's procedures and the current laboratory director failed to be signed and date the procedures (see D-5403).