Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	07D0099572	09/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Bridgeport Hospital Laboratory	267 Grant St, Bridgeport, CT	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on the review of laboratory policies and procedures and interviews it was determined that the laboratory failed to maintain quality control material for at least two years. Findings include: 1. The laboratory procedure titled QUALITY CONTROL EVALUATION OF THE STAIN AND SLIDE PREPARATION stated that a buccal smear was run each day on the automatic stainer to evaluate the quality and stain characteristics of the Papanicolaou stain. a. The Survey Team requested and the laboratory failed to provide any of the stained buccal smear slides, used to assess the quality and characteristics of the Papanicolaou stain, prior to 8/28/18. 2. During an interview on 9/11/18 at 8:30 AM Cytotechnologist #2 stated that the stained buccal smear slides were discarded after two to three weeks. 3. These findings were reviewed with and confirmed by the Laboratory Director/Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/11/18 at 4:30 PM.
D5032	CYTOLOGY CFR(s): 493.1221 If the laboratory provides services in the subspecialty of Cytology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299.

	This CONDITION is not met as evidenced by: Based on the review of written procedures, record review, surveyor interviews, and observation the laboratory failed to ensure that rapid stain effusion slides were maintained and available for review (refer to D5203); failed to follow written procedures for processing urine and effusion specimens (refer to D5401); failed to establish written procedures for the rapid stain assessment, the non-gynecologic Papanicolaou stain assessment, and safety cabinet maintenance (refer to D5403); failed to ensure that two of five pathologists had Becton Dickinson (BD) SurePath morphology training and failed to follow manufacturer's guidelines for BD SurePath processors (refer to D5411); failed to establish performance specifications when the laboratory modified the BD SurePath test system (refer to D5423); failed to ensure that the required maintenance was performed on the Shandon Cytospin and two Hettich centrifuges (refer to D5429); failed to assess the rapid fine needle aspiration stain and Papanicolaou stain materials each day of use (refer to D5473); failed to follow written procedures to ensure that corrected reports indicated the basis for correction (refer to D5659); and failed to ensure that the corrected report dates were designated on corrected laboratory reports. The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results in the subspecialty of Cytology.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on the review of laboratory policies and procedures and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that the rapid stain effusion slides were maintained to ensure the optimum integrity of a patient's specimen from collection through reporting of results. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written policy or procedure to ensure that all specimen slides were maintained by the laboratory and available for review. 2. The laboratory procedure titled PROTOCOL FOR SPECIMENS WITH A HIGH POTENTIAL FOR CROSS CONTAMINATION RAPID STAIN -EFFUSION PROTOCOL stated that one slide from each effusion prepared with direct smears would be stained with Methylene Blue to assess for cellularity or malignancy. The procedure did not designate that the Methylene Blue slides would be maintained and stored to ensure the optimum integrity of a patient's specimen. 3. The Survey Team reviewed one cytology fluid report (NB18-51) and corresponding slides. The report stated that the specimen had a rapid stain slide, two Papanicolaou stained slides, and one cell block slide. a. The laboratory failed to provide one of four slides. The rapid stain slide was not available for review. 4. Cytotechnologist #2 stated during an interview on 9/11/18 at 8:25 AM the the rapid stain slides were only maintained for two to three weeks. The slides were kept on a 20 slide storage tray and when the tray was full, the slides were discarded. 5. These findings were reviewed with and confirmed by the Laboratory Director/Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/11/18 at 4:30 PM.

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 the review of eighty laboratory policies and procedures, observation, and interview it was determined that the laboratory failed to follow written procedures for two laboratory processes. Findings include: 1. The laboratory failed to follow the written procedure titled NON-GYN PROCESSING OUTLINE which stated that two direct smears or four cytospins were made on urine cytology specimens. a. On 9/10/18 at 10:15 AM the Survey Team observed Cytopreparatory Technician #1 process seven urine cytology specimens. The specimens were processed with the BD SurePath technique. Direct smears or cytospin slides were not prepared. Specimens include: -NB18-1749 -NB18-1750 -NB18-1751 -NB18-1752 -NB18-1753 -NB18-1754 -NB18-1755 2. The laboratory failed to follow the written procedure titled PROTOCOL FOR DIRECT SMEARS which stated that two direct smears were made on effusion specimens when there was sufficient cellular material. a. During an interview on 9/11 /18 at 12:45 PM Cytotechnologist #2 stated that four smears were made on effusion specimens with sufficient cellular material. 3. These findings were reviewed with and confirmed by the Laboratory Director/Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/13/18 at 1:00 PM.
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 the review of eighty laboratory policies and procedures, laboratory records, and interview it was determined that the laboratory failed to have written procedures for three laboratory processes. Findings include: 1. The Survey Team requested and

	the laboratory failed to provide a written procedure for the assessment of the staining characteristics of the Rapid Hematoxylin and Eosin stain each day of use. 2. The Survey Team requested and the laboratory failed to provide a written procedure for the assessment of the staining characteristics of the manual non-gynecologic Papanicolaou stain each day of use. 3. The Survey Team requested and the laboratory failed to provide a written procedure for the daily operation, disinfection/cleaning, and maintenance of the VBM-600 BAKER biological safety cabinet. 4. These findings were reviewed with and confirmed by the Laboratory Director/Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/13 /18 at 1:00 PM.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: A. Based on the review of the BD SUREPATH IMPLEMENTATION GUIDE, review of certification records for the BD SurePath Pap Test, and interview it was determined that the laboratory failed to ensure that two of five Technical Supervisors had received the appropriate training to evaluate gynecologic specimens using the BD SurePath Pap Test, according to the manufacturer's instructions. Findings include: 1. The BD SUREPATH IMPLEMENTATION GUIDE states that the "BD Surepath Morphology Training" must be completed for cytotechnologists and pathologists who evaluate BD SurePath prepared slides. a. The Survey Team requested and the laboratory failed to provide morphology training records for two of five Technical Supervisors who performed diagnostic interpretations on BD SurePath Pap Tests. There were no training records for: - Technical Supervisor #3 - Technical Supervisor #4. 2. These findings were reviewed with confirmed by the Laboratory Director /Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/12/18 at 3:40 PM. B. Based on review of the BD CYTORICH NON-GYN APPLICATIONS PROCEDURES AND PROTOCOLS operator's manual, observation, laboratory policies and procedures, and interviews it was determined that the laboratory failed to follow the manufacturer's instructions for processing non-gynecologic cytology specimens using the BD SurePath Processor. Findings include: 1. The BD CYTORICH NON-GYN PROCEDURES AND PROTOCOLS operator's manual states the following: "STEP II. FIXATION #6. Add 30 ml of BD CytoRich Red Preservative. #7. Vortex for 15 +/- 5 seconds and allow to sit for a minimum of 30 minutes. STEP III. WASH #10. If no visible or small pellet is identified, add 10 ml of buffered DI H2O directly to the 50 ml centrifuge tube, vortex for 15 +/- 5 seconds and transfer entire contents to 12 ml tube. #11. If a moderate to large pellet is identified transfer a representative sample (1-5 drops) to 12 ml tube and add 10 ml buffered DI H2O." 2. On 9/10/18 at 10:15 AM the Survey Team observed Cytopreparatory Technician #1 process seven urine cytology specimens. Specimens include: -NB18-1749 -NB18-1750 -NB18-1751 -NB18-1752 -NB18-1753 -NB18-1754 -NB18-1755 a. Cytopreparatory Technician #1 failed to allow the specimen to sit for 30 minutes after the CytoRich Red was added. The 30 minute fixation step was omitted. b. Cytopreparatory Technician #1 failed to evaluate the cell pellet and failed to perform the required wash step. 3. The laboratory written procedure titled

	PROTOCOL FOR URINE PREPARATION USING SUREPATH LIQUID BASED TECHNOLOGY did not include a 30 minute fixation step or a buffered DI H2O wash step. 4. Cytopreparatory Technician #1 stated in an interview on 9/10/18 at 10:30 AM that the specimens were not allowed to sit for 30 minutes after the CytoRich Red was added and that a wash step was not performed. This was confirmed by Cytotechnologist #2 during an interview on 9/11/18 at 10:45 AM. 5. These findings were reviewed with and confirmed by the Laboratory Director/Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/11 /18 at 4:30 PM. C. Based on review of the PREP STAIN SLIDE PROCESSOR - OPERATOR'S MANUAL 780-13000-00, observation, laboratory policies and procedures, and interviews it was determined that the laboratory failed to ensure that the reagents required by the manufacturer for processing specimens on the BD SurePath Processor were used. Findings include: 1. The PREP STAIN SLIDE PROCESSOR - OPERATOR'S MANUAL 780-13000-00 states the following: "The Settling chamber is emptied and then rinsed with PrepStain Alcohol Blend Rinse." The Alcohol Blend is equal parts: - 100% Reagent Alcohol (denatured ethanol) or 100% Ethanol -100% 2-Propanol (isopropyl alcohol). a. On 9/10/18 at 10:30 AM the Survey Team observed that a one gallon container labeled Ethyl Alcohol 200 proof was being used in place of the Alcohol Blend. 2. The laboratory written procedures titled GYN PROCESSING - SUREPATH METHOD and PROTOCOL FOR URINE PREPARATION USING SUREPATH LIQUID BASED TECHNOLOGY did not list Alcohol Blend under the materials required for the PrepStain Processor. 3. Cytotechnologist #2 stated during an interview on 9/11/18 at 8:35 AM that the laboratory used Ethyl Alcohol 200 proof for rinsing the Settling Chambers and not the Alcohol Blend as required by the manufacturer. 4. These findings were reviewed with and confirmed by the Laboratory Director/Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/11/18 at 4:30 PM.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation and interview it was determined that the laboratory failed to ensure that all reagents and solutions were labeled to indicate content. Findings include: 1. The Survey Team observed that seventeen of twenty-four tubes with clear fluid located on the counter by the the "GYN and URINE" centrifuge were not labeled to indicate content. 2. The Survey Team observed that one of fifteen 15 ml tubes with blue fluid located on the counter by the "NON-GYN" centrifuge were not labeled to indicate content. 3. These findings were reviewed with and confirmed by the Laboratory Director/Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/11/18 at 4:30 PM.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
A. Based on review of the BD CYTORICH NON-GYN APPLICATIONS PROCEDURES AND PROTOCOLS operator's manual, observation, policies and procedures, and interview it was determined that the laboratory failed to establish performance specifications when the laboratory modified the BD SurePath test system manufacturer's instructions with an alternate method of processing cytology specimens. Findings include: 1. The laboratory failed to establish performance specifications or evidence that the accuracy, precision, analytical sensitivity and specificity of the modified BD SurePath procedures and test results was adequate to provide accurate diagnostic interpretations. 2. The BD CYTORICH NON-GYN PROCEDURES AND PROTOCOLS operator's manual states the following: "STEP II. FIXATION #6. Add 30 ml of BD CytoRich Red Preservative. #7. Vortex for 15 +/- 5 seconds and allow to sit for a minimum of 30 minutes. STEP III. WASH #10. If no visible or small pellet is identified, add 10 ml of buffered DI H2O directly to the 50 ml centrifuge tube, vortex for 15 +/- 5 seconds and transfer entire contents to 12 ml tube. #11. If a moderate to large pellet is identified transfer a representative sample (1-5 drops) to 12 ml tube and add 10 ml buffered DI H2O." 3. On 9/10/18 at 10:15 AM the Survey Team observed Preparatory Technician #1 process seven urine cytology specimens with an alternate method. Specimens include: -NB18-1749 -NB18-1750 -NB18-1751 -NB18-1752 -NB18-1753 -NB18-1754 -NB18-1755 a. Cytopreparatory Technician #1 failed to allow the specimen to sit for 30 minutes after the CytoRich Red was added. The 30 minute fixation step was omitted. b. Cytopreparatory Technician #1 failed to evaluate the cell pellet and failed to perform the required wash step. 4. The laboratory written procedure titled PROTOCOL FOR URINE PREPARATION USING SUREPATH LIQUID BASED TECHNOLOGY did not include a 30 minute fixation step or a buffered DI H2O wash step. 5. Cytopreparatory Technician #1 stated in an interview on 9/10/18 at 10:30 AM that the specimens were not allowed to sit for 30 minutes after the CytoRich Red was added and that a wash step was not performed. This was confirmed by Cytotechnologist #2 during an interview on 9/11/18 at 10:45 AM. 6. These findings were reviewed with and confirmed by the Laboratory Director/Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/11/18 at 4:30 PM. B. Based on review of the PREP STAIN SLIDE PROCESSOR - OPERATOR'S MANUAL 780-13000-00, observation, laboratory policies and procedures, and interviews it was determined that the laboratory failed to establish performance specifications when the laboratory modified the BD SurePath test system manufacturer's instructions by using an alternate reagent when processing cytology specimens. Findings include: 1. The laboratory failed to establish performance specifications or evidence that the accuracy, precision, analytical sensitivity and specificity of the modified BD PrepStain slide processor procedures and test results was adequate to provide accurate diagnostic interpretations. 2. The PREP STAIN SLIDE PROCESSOR - OPERATOR'S

	MANUAL 780-13000-00 states the following: "The Settling chamber is emptied and then rinsed with PrepStain Alcohol Blend Rinse." The Alcohol Blend is equal parts: -100% Reagent Alcohol (denatured ethanol) or 100% Ethanol -100% 2-Propanol (isopropyl alcohol). a. On 9/10/18 at 10:30 AM the Survey Team observed that a one gallon container labeled Ethyl Alcohol 200 proof was being used in place of the Alcohol Blend as an alternate method. 3. The written laboratory procedures titled GYN PROCESSING - SUREPATH METHOD and PROTOCOL FOR URINE PREPARATION USING SUREPATH LIQUID BASED TECHNOLOGY did not list Alcohol Blend under the materials required for processing. 4. Cytotechnologist #2 stated during an interview on 9/11/18 at 8:35 AM that the laboratory used Ethyl Alcohol 200 proof for rinsing the Settling Chambers and not the Alcohol Blend as required by the manufacturer. 5. These findings were reviewed with and confirmed by the Laboratory Director/Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/11/18 at 4:30 PM.
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: A. Based on observation, the lack of laboratory records, and interviews it was determined that the laboratory failed to ensure that the required maintenance on the Shandon Cytospin 4 was performed, as specified by the manufacturer, for any date in 2017 and to the date of the survey in 2018. Findings include: 1. On 9/11/18 at 10:30 AM the Survey Team observed one Shandon Cytospin 4 in the laboratory. 2. The Survey Team requested and the laboratory failed to provide any maintenance logs or records of daily, weekly, and monthly equipment maintenance required by the manufacturer for the Shandon Cytospin 4 for any date in 2017 and to the date of the survey in 2018. 3. Cytotechnologist #3 confirmed during an interview on 9/11/18 at 10:30 AM that there were no daily, weekly, or monthly maintenance tasks performed on the Shandon Cytospin 4 and that the only maintenance performed was an annual preventative maintenance check. 4. These findings were reviewed with and confirmed by the Laboratory Director/Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/11/18 at 4:30 PM. B. Based on observation, the lack of laboratory records, and interviews it was determined that the laboratory failed to ensure that the required maintenance on two of two Hettich Centrifuges was performed, as specified by the manufacturer, for any date in 2017 and to the date of the survey in 2018. Findings include: 1. On 9/11/18 at 10:30 AM the Survey Team observed two Hettich Centrifuges in the laboratory. 2. The Survey Team requested and the laboratory failed to provide any maintenance logs or records of the daily, weekly, and monthly equipment maintenance required by the manufacture for the Hettich Centrifuges for any date in 2017 and to the date of the survey in 2018. 3. Cytotechnologist #3 confirmed during an interview on 9/11/18 at 10:30 AM that there were no daily, weekly, or monthly maintenance tasks performed on the Hettich centrifuges and that the only maintenance performed was an annual preventative maintenance check. 4. These findings were reviewed with and confirmed by the Laboratory Director/Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/11/18 at 4:30 PM. C. Based on the review of laboratory records and interview it was determined that the laboratory failed to ensure

	that the required monthly maintenance tasks on the Becton Dickinson (BD) Prep Stain equipment Maintenance were performed and documented in 2017 and to the date of the survey in 2018. Findings include: 1. On 9/11/18 at 10:30 AM the Survey Team observed a BD SurePath PrepStainer in the laboratory. 2. The Survey Team reviewed the forms titled PREP STAIN MAINTENANCE LOG from January 2017 through August 2018. a. The Survey Team requested and the laboratory failed to provide documentation that the monthly maintenance tasks were performed in January 2017 and failed to provide documentation for the date or personnel that performed the monthly tasks in June 2018. 3. These findings were reviewed with and confirmed by the Laboratory Director/Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/11/18 at 4:30 PM.
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 the review of laboratory records and interview it was determined that the laboratory failed to test staining materials for intended reactivity to ensure predictable staining characteristics for the Rapid Hematoxylin and Eosin stain and the manual Papanicolaou stain each day of use in 2017 and to the date of the survey in 2018. Findings include: 1. The Survey Team requested and the laboratory failed to provide stain assessment records for the Rapid Hematoxylin and Eosin stain used for fine needle aspiration specimens. 2. The Survey Team requested and the laboratory failed to provide stain assessment records for the manual Papanicolaou stain used for non-gynecologic fluid specimens. 3. During an interview on 9/11/18 at 8:10 AM Cytotechnologist #1 confirmed that there were no laboratory records to document the staining characteristics of the Rapid Hematoxylin and Eosin staining or the manual Papanicolaou staining performed for each day of use in 2017 and to the date of the survey in 2018. 4. These findings were reviewed with and confirmed by the Laboratory Director/Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/11/18 at 4:30 PM.
D5659	CYTOLOGY CFR(s): 493.1274(e)(6) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(6) Corrected reports issued by the laboratory indicate the basis for correction. This STANDARD is not met as evidenced by: Based on the review of laboratory policies and procedures, two corrected cytology reports, and interview it was determined that the laboratory failed to follow the written procedure to ensure that corrected reports indicated the basis for correction. Findings include: 1. The laboratory failed to follow the written procedure titled SIGNIFICANT CORRECTION OF LABORATORY RESULTS which stated under ANATOMIC

	PATHOLOGY 1.1: "The reasons for revision are explained in the report." a. The Survey Team reviewed two corrected (amended) reports that had a change in diagnosis. -NB17-1836 -CB18-513 b. The reports did not include or reference the original diagnosis to ensure that the basis for correction was on the report. 2. These findings were reviewed with and confirmed by the Laboratory Director/Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/11/18 at 4:30 PM.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of laboratory policies and procedures, laboratory records, and interviews it was determined the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the analytic phases of cytology testing. Cross refer to D5411, D5423, D5429, D5473, and D5659
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 the review of policies and procedures, corrected cytology reports, and interview it was determined that the laboratory failed to have a policy or procedure to ensure that the corrected report date was clearly designated on three of three corrected cytology reports. Findings include: 1. The Survey Team requested and the laboratory failed to provide a written procedure to ensure that the "date reported" on corrected reports was clearly defined as the corrected report date. a. The written procedure titled SIGNIFICANT CORRECTION OF LABORATORY RESULTS failed to include a method of entering the corrected report data into the Laboratory Information System (LIS) to ensure that the corrected report date was clearly designated. 2. Three of three corrected reports reviewed did not designate that the report date was the date of the corrected report. Corrected reports include: NB17-1040 NB17-1836 CB18-513 3. These findings were reviewed with and confirmed by the Laboratory Director /Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/11/18 at 4:30 PM.

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 review of laboratory policies and procedures, record review, observation, and surveyor interviews it was determined that the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to fulfill the responsibility for the overall operation of the laboratory and failed to ensure compliance with applicable regulations (refer to D6079), failed to ensure that quality assessment programs were established (refer to D6094), and failed to ensure that three of five Technical Supervisors had received the training required to evaluate BD SurePath Specimens (refer to D6102). The cumulative effect of these systemic problems resulted in the Laboratory Director's inability to provide overall management and direction of cytology in accordance with 493.1445 of this subpart.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, review of laboratory records, observation, and interviews it was determined that the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory, to include assuring compliance with the applicable regulations and ensuring that all the duties of the Laboratory Director were performed. Cross refer to D3031, D5203, D5401, D5403, D5411, D5415, D5423, D5429, D5473, D5659, and D5805.
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 laboratory policies and procedures, review of laboratory records, observation, and interviews it was determined that the Laboratory Director failed to ensure that quality assessment programs were established to assure the quality of laboratory services and identify failures in quality as they occur. Cross refer to D5791
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the review of the BD SUREPATH IMPLEMENTATION GUIDE, review of certification records, and interviews it was determined that the Laboratory Director failed to ensure appropriate training according to the manufacturer's instructions. Two of five Technical Supervisors had not received the appropriate training to evaluate the BD SurePath Pap Test. Findings include: 1. The BD SUREPATH IMPLEMENTATION GUIDE states that the "BD Surepath Morphology Training" must be completed for cytotechnologists and pathologists who evaluate BD SurePath prepared slides. a. The Survey Team requested and the laboratory failed to provide morphology training records for two of five Technical Supervisors who performed diagnostic interpretations on BD SurePath Pap Tests. There were no training records for: - Technical Supervisor #3 - Technical Supervisor #4 2. These findings were reviewed with and confirmed by the Laboratory Director/Technical Supervisor #1, Technical Supervisor #2, and Technical Supervisor #3 during an interview on 9/12/18 at 3:40 PM.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: A. Based on the review of 320 routine negative gynecologic cases (322 slides) from January 2018 through May 2018 and confirmation by the Technical Supervisor #3 on September 13, 2018 it was determined that the Technical Supervisor failed to verify the accuracy of one gynecologic test. 1. CB18-91 1/28/18 SurePath Pap Test (SPPT) LABORATORY DIAGNOSIS: Negative for Intraepithelial Lesion Atrophic Smear Severe Acute Inflammation SURVEY TEAM DIAGNOSIS: Unsatisfactory for Interpretation Scant Cellularity TECHNICAL SUPERVISOR DIAGNOSIS: Unsatisfactory for Interpretation Scant Cellularity B. Based on the review of 237 non-gynecologic cases (543 slides) from January 2018 and February 2018 and confirmation by the Technical Supervisor #3 on September 13, 2018 it was determined that the Technical Supervisor failed to verify the accuracy of two non-gynecologic tests. 1. NB18-152 1/22/18 Urine LABORATORY DIAGNOSIS: Predominantly Squamous Cells showing Low Grade Intraepithelial Lesion Consistent

	with Vaginal Contamination Crystals Present Acute Inflammation Red Blood Cells SURVEY TEAM DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion Herpes Virus TECHNICAL SUPERVISOR DIAGNOSIS: Low Grade Squamous Intraepithelial Lesion Herpes Virus 2. NB18-125 1/1/8/19 Pelvic Wash LABORATORY DIAGNOSIS: Non-Diagnostic Blood SURVEY TEAM DIAGNOSIS: Negative for Malignancy TECHNICAL SUPERVISOR DIAGNOSIS: Negative for Malignancy Scant Cellularity
D9999	By agreement between ASCT Services, Inc. and CMS, information provided for CMS's completion of CMS Form 670 are ASCT Services, Inc. averages only. This information is confidential and proprietary to ASCT Services, Inc., is exempt under the Freedom of Information Act (5 U.S.C. 552 et seq.), and shall be used for federal government purposes only.