Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 07D0099572	**(X3) Date Survey Completed** 07/20/2018
Name of Provider or Supplier Bridgeport Hospital Laboratory	**Street Address, City, State** 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
D0000	An on-site complaint investigation of the Bridgeport Hospital Laboratory was conducted pursuant to 42CFR Part 493 of the Clinical Laboratory Improvement Amendments (CLIA) of 1988.
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 surveyor observation, record review and staff interview, the cytology laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1274, and 493.1281 through 493.1299. The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results. Refer to D5203, D5209, D5311, D5313, D5393, D5403, D5407, D5411, and D5821.
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: A. Based on record review and staff interview, the laboratory failed to establish and

follow written policies and procedures to ensure positive identification and correct orientation of specimens and slides while utilizing the SurePath liquid based technology in the subspecialty of cytology. Findings include: 1. Staff interview with pathologist #2 (P2) on 7/3/18 at 10:17 AM revealed, a) 8 of 12 patients had their slides switched with each other during slide preparation. P2 stated during specimen processing and slide preparation, the cytology prep technician loaded the slides incorrectly which resulted in the switching of 8 samples. This resulted in an incorrect positive GYN smear for Patient #1 and an incorrect negative urine cytology result for Patient #2. b) Urine and PAPs were switched because the tray was loaded backwards. c) Corrective action instituted included posting a stop sign for no one to enter the room; switched phone system so it won't ring during processing and dots added to tray for slide location. 2. Record review on 7/3/18 of the 'PrepStain Slide Processor 780-06181-00 Rev B Operator' manual revealed the following: Chapter 4 PreProcessing Steps, Chain of custody section states: a) "In order to maintain chain of custody of test samples, all specimen vials, centrifuge tubes, and glass slides are loaded in their respective racks front to back and left to right. b) Warning: Tubes in centrifuge racks must be carefully oriented with matching slide racks. Correct placement of labeled tubes with correspondingly labeled slides is essential and must be verified by the operator in order to prevent sample mix-ups. c) Positioning pins on the PrepMate rack and PrepStain instrument help to ensure proper alignment. This insures the sample from position 1 in the PrepMate rack is deposited on the slide in position 1 on the slide rack." 3. Record review on 7/3/18 of the 'GYN Processing Surepath' procedure, effective Feb. 2006 revealed the following: a) The procedure was approved and signed by the cytology technical supervisor (CTS) on 8/11/06. b) A statement regarding the proper orientation of samples throughout processing and staining was not included. 4. Record review of the cytology procedures for urine specimens on 7/3/18 revealed the following: a) The first documented written procedure, 'Urine Cytology Prep using SurePath' was effective and signed on 6/21/16 by the CTS. b) A statement regarding the proper orientation of samples throughout processing and staining was not included. 5. Staff interview with cytotechnologist #2 (CT2) on 7/3/18 at 9:39 AM revealed: a) The tray can only be loaded onto the instrument one way. CT2 loaded specimens onto the tray and had to turn the tray around in order to load it onto the SurePath instrument. This resulted in the specimens in the outside rows of the tray being switched with each other. b) CT2 had only been employed for 9 months and only processed specimens when the full-time cytology prep tech had the day off, (approximately once every 2 weeks). c) It was a busy day with many specimens, a fine needle aspirate and the phone was ringing. B. Based on record review and staff interview, the laboratory failed to establish and follow written policies and procedures per manufacturer's instructions to utilize separate programs for different specimen types on the SurePath PrepStain Slide Processor in the subspecialty of cytology. Findings include: 1. Record review on 7/3/18 of the 'PrepStain Slide Processor 780-06181-00 Rev B Operator' manual revealed the following: Chapter 4 PreProcessing Steps, Chain of custody section states, Appendix C, 'Non-GYN Slide Processing' details the use of the PrepStain Non-GYN application to process Non-GYN specimen slides. 2. Record review on 7/3/18 of the 'Protocol for Urine Preparation using Surepath Liquid Based Technology' procedure revealed, urine samples are run on the "PrepStain per protocol using gynecological software." 3. Record review on 7/20/18 of the CoPath Specimen Search report revealed the first urine cytology specimen was processed utilizing the Surepath CytoRich Clear Preservative on 11/23/15. 4. Record review of the cytology procedures for urine specimens on 7/3/18 revealed the following: a) The first documented written procedure, 'Urine Cytology Prep using SurePath' was effective and signed on 6/21/16 by the CTS. b) A statement to process urines separate or together with gynecological specimens was not included. 5. During

	staff interview with pathologist #2 (P2) on 7/3/18 at 2:39 PM, P2 stated "GYN and urine cytology specimens were always put together on the same tray for efficiency and cost effectiveness." 6. Staff interview with cytology prep tech #1 (CPT1) on 7/20 /18 at 10:00 AM confirmed the above findings. CPT1 further stated: a) Handwritten notes from the training session for urine specimens with the manufacturer representative were initially utilized while a written procedure was being written. b) A manufacturer procedure was not available for use while a procedure was being written. 7. Staff interview with Pathologist #1 (P1) on 7/3/18 at 9:00 AM revealed: a) P1 is the CTS. b) P1 was unaware that urine and gynecological specimens were run together on the Surepath PrepStain instrument utilizing the same program. c) P1 would not have signed and approved a procedure that allowed GYN and urine specimens to be run together. d) P1 put a stop to the process once P1 became aware of it. e) P1 did not check to see if they were run together or separate because P1 assumed they were run separately. f) CPT1 performs the competency assessments on the staff performing urine and GYN specimen preparation, processing and staining. 8. The laboratory processed 1,564 urine cytology specimens on the same run as gynecological specimens from 11/23/15 until corrective action was instituted on 8/22 /17 due to switched samples.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to establish and follow written policies and procedures to assess the competency of the technical supervisor (TS), general supervisor (GS) and clinical consultant (CC) based on the regulatory responsibilities. Findings include: 1. Review of the laboratory's 'Professional Levels and Responsibilities' policy on 7/11/18 revealed: a) "It is the policy of Bridgeport Hospital to hire Testing Personnel who are qualified under CLIA to perform High Complexity testing and to act as GS in the absence of Manager Staff. b) The laboratory job description/performance evaluations are based on the CLIA responsibilities." c) The policy did not establish a frequency for evaluation. d) The policy did not address the competency evaluation for the CC, TS and TC. 2. Record review of the 'Technical Competency' policy on 7/11/18 revealed: a) "The performance of section directors/technical supervisors, general supervisors and technical consultants is assessed by the administrative manager or laboratory medical director and all are reviewed by the laboratory medical director." b) The policy did not establish a frequency for evaluation. c) The policy did not state the evaluations are based on the CLIA responsibilities. 3. Record review on 7/11/18 of the laboratory's 2016, 2017 and 2018 competency records revealed: a) Competency documentation for the CC was not available. b) Competency documentation for 5 of 6 TS based on regulatory responsibilities was not available. c) Competency documentation for 1 of 1 TC based on regulatory responsibilities was not available. d) Competency documentation for 16 of 19 GS based on regulatory responsibilities was not available. 4. Staff interview with the laboratory director on 7/11/18 at 3:00 PM confirmed the laboratory did not have a policy to assess all laboratory positions based on CLIA responsibilities and they were not assessed.

D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: A. Based on surveyor observation, record review, and staff interview, the laboratory failed to follow written policies and procedures for preparation and processing gynecological specimens utilizing SurePath liquid based technology. Findings include: 1. Surveyor observation on 7/11/18 at 9:05 AM of the accessioning, processing, and staining of gynecological SurePath specimens as compared to the written procedure revealed: a) Cytology prep technician #1 (CPT1) did not follow the procedure as written. CPT1 omitted and added steps to the procedure. b) CPT1 performed steps out of order. c) CPT1 utilized BD SurePath Collection vials not described in the urine cytology procedures. 2. Staff interview on 7/11/18 at 10:30 AM with CPT1 confirmed the above findings. B. Based on surveyor observation, record review and staff interview, the laboratory failed to establish written policies and procedures for preparation and processing urine specimens utilizing SurePath liquid based technology before patient testing and failed to follow the procedure once established. Findings include: 1. Surveyor observation on 7/11/18 at 11:00 AM of the accessioning, processing, and staining of urine SurePath specimens as compared to the written procedure revealed: a) CPT1 did not follow the procedure as written. b) CPT1 omitted and added steps to the procedure. c) CPT1 performed steps out of order. 2. Record review on 7/20/18 of the CoPath Specimen Search report revealed, the first urine cytology specimen processed utilizing the Surepath CytoRich Clear Preservative was on 11/23/15. 3. Record review of the cytology procedures for urine on 7/3/18 revealed the following: a) The first documented written procedure, 'Urine Cytology Prep using SurePath' was effective on 6/21/16. b) The procedure failed to include specimen storage and preservation. 4. Staff interview on 7/11/18 at 11:22 AM with CPT1 confirmed the above findings. CPT1 further stated: a) Handwritten notes from the training session for urine specimens with the manufacturer representative were first utilized while a written procedure was being written. b) A manufacturer procedure was not available to use while a procedure was being written.
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on surveyor observation, record review and staff interview, the laboratory failed to ensure the date and time of specimen receipt is documented in the subspecialty of cytology. Findings include: 1. Surveyor observation on 7/11/18 at 9:50 AM of the cytology specimen log in and ordering process revealed, the date and time a specimen is received is not consistently documented by the laboratory. 2. Record review on 7/11/18 revealed 1 of 3 urine cytology requisition forms did not include the

	date and time the specimen was received by the laboratory. 3. Staff interview with cytology prep tech #1 (CPT1) on 7/11/18 at 9:50 AM confirmed the specimen in Finding #2 above did not have the date and time of receipt documented. CPT1 stated, "Specimens that are dropped off after hours are left in a basket in the main laboratory until the next morning." 4. During staff interview with pathologist #2 (P2) on 7/11/18 at 1:30 PM, P2 stated, "Specimens that are dropped off after hours are left in a basket until the next morning and it is difficult to ensure the date and time of receipt is documented."
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems 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 preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to revise policies and procedures, document and monitor corrective action for effectiveness to prevent recurrence of preanalytic problems and document notification of staff in the subspecialty of cytology. Finding include: 1. Staff interview with pathologist #2 (P2) on 7/3/18 at 10:17 AM revealed, 8 of 12 patients had their slides switched during slide preparation. 2. Record review on 7/3/18 of the hospital RCA Event:Cytology Specimen Mismatch, July 10, 2017, Date of RCA: August 28, 2017, Corrective Action Plan located in the hospital Performance Management department, revealed: a) 'Root Cause': Processing urine and GYN specimens on the same slide tray. b) 'Corrective Action Plan:' "Perform all urine and GYN specimen processing separately i. GYN specimens will be processed at different times and on separate slide trays from the urine specimens. ii. Will add a double check verification process prior to specimens running through the "Prep Stain" process. Verifier will check that the information (Accession # and the patient's name) on the centrifuge tubes matches the information on the corresponding slides (e.g. info on tube in slot 1 on the centrifuge tube holder matches info on slide in slot 1 on tray and so on. iii. Red marking placed on slide tray to indicate start for position 1." c) 'Who/Time Frame Status Updates': Cyto Prep Tech will start 8/29/17. d) 'Root Cause:' Distractions i. "Tech having to answer phone calls, Assisting other staff with issues, leaving lab to assist with FNA ..." e) 'Corrective Action Plan:' i. "Will educate administrative staff to screen phone calls and triage information .... ii. Educate central processing staff on a designated where to leave specimens. iii. Institute STAR decal to act as a stop zone for interruptions when techs are in the midst of processing specimens. Lab staff will need to be educated on new process change." f) 'Who/Time Frame Status Updates:' "Manager; education to start 8/29/17." 3. Record review on 7/3/18 of the cytology performance improvement program records for June 2017 through September 2017 revealed, documentation for the above mix-up was not available. 4. Record review on 7/3/18 of the laboratory's 'Quality Assurance Minutes Date September 7, 2017', cytology section revealed: a) "Pathologist #1 (P1) presented June and July data. b) P1 would like discrepancy sheets so he/she can fill in QA section sheets. c) Laboratory manager (LM) will speak the cytotechnologist #3 to locate and get them printed for P1. d) Everyone in cytology will be having competency review per manager." 5. Record review on 7/11/18 of an untitled excel spreadsheet received from the LM

	revealed, "cytology specimen switched at processing. RCA investigation with RM 8 /21/17." 6. Record review on 7/3/18 of the laboratory's, 'GYN Processing, Surepath Method' procedure revealed: a) The policy was not updated until 6/21/18 with the following: "Verification of proper positioning of tubes and slides is performed by a second individual and accession numbers are recorded and initials are placed on the GYN/Anal Surepath Tube/Slide Verification Monthly Sheet." b) The following RCA corrective actions were not included in the procedure: i. Perform all urine and GYN specimen processing separately. ii. Red marking placed on slide tray to indicate start for position 1. iii. Institution of the STAR decal to act as a stop zone for interruptions when techs are in the midst of processing specimens. 7. Record review on 7/3/18 of the 'Protocol For Urine Preparation Using Surepath Liquid Based Technology' procedure revealed: a) The policy was not updated until 6/21/18 with the following: "Verification of proper positioning of tubes and slides is performed by a second individual and accession numbers are recorded and initials are placed on the NONGYN (Urine) Surepath Tube/Slide Verification Monthly Sheet." b) The following RCA corrective actions were not included in the procedure: i. Perform all urine and GYN specimen processing separately. ii. Red marking placed on slide tray to indicate start for position 1. iii. Institution of the STAR decal to act as a stop zone for interruptions when techs are in the midst of processing specimens. 8. Record review on 7/11/18 of the laboratory's training documentation for 2017 and 2018 revealed: a) Notification and Staff retraining documentation was not available for 5 of 5 cytology personnel. b) Documentation of the education of administrative staff to screen phone calls; central processing staff as to where to leave samples; laboratory staff as to the STAR Decal; and cytology staff as to the procedure to follow when only one staff is available for processing was not available. 9. During staff interview on 7 /11/18 at 4:00 PM, the LM stated, the spreadsheet indicated in # 5 above was the only QA record for this case in the laboratory. 10. Staff interview with the laboratory director on 7/11/18 at 4:05 PM confirmed: a) Notification and retraining for 5 of 5 cytology personnel was not documented. b) Documentation of the education of administrative staff, central processing staff, laboratory staff and the STAR Decal was not available. c) The procedure manual was not updated at the time of the corrective action plan as required in the RCA for the processing separately of GYN and urine specimens to prevent recurrence. d) When the procedure was updated on 6/21/18, all of the changes required in the RCA for the processing of GYN and urine specimens to prevent recurrence were not added. e) Laboratory follow-up was not performed to ensure all corrective action was completed as noted in the RCA.
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:
A. Based on surveyor observation and staff interview, the laboratory failed to have step by step specimen processing and staining procedures including slide preparation, reagents, stains, solutions and other materials used for SurePath gynecological specimens in the subspecialty of cytology. Findings include: 1. Surveyor observation on 7/11/18 at 9:00 AM of the cytology processing and staining area revealed reagents, stains and equipment are missing as compared to the written procedure 'GYN Processing-SurePath Method' as follows: a) BD SurePath Collection vials are utilized for gynecological specimens. b) 2 identical unlabeled Rotina 380 centrifuges sitting side by side. c) Staining Reagents in use are Hematoxylin stain, EA/OG Combo Stain, Buffered Water and 100% Ethyl Alcohol. d) Current software version in the Prep-stain Processor is 1.3.0.3. e) Hooded area for coverslipping containing 100% ethanol and xylene staining dishes, mounting medium, coverslips and kimwipes. 2. Surveyor observation on 7/11/18 at 09:05 AM of the accessioning, processing, staining of gynecological specimens as compared to the written procedure 'GYN Processing-SurePath Method' revealed cytology prep technician #1 (CPT1) either omitted, added or performed steps out of order as follows: a) Verification of proper positioning was done out of order. b) Labeling of test tubes and placement into PrepMate testing rack was done prior to HPV processing. c) The procedure does not indicate which centrifuge contains the program corresponding to the procedure in use. d) The Rotina centrifuge on the left contains programs 1 and 2 from the GYN procedure. e) When the start button on the centrifuge is pressed, the program is called up. The start button must be hit a second time to start the centrifuge. f) Vortexing was omitted. g) When the supernatant is aspirated: i. A vacuum with disposable tips connected to a block is utilized. ii. CPT1 was careful to slide the tips down the side of the tube and wait until no liquid remained in the tube. iii. Unused tips were put back in the box for reuse. h) CPT1 decanted specimens into the sink then counted to 3, then blotted specimens and recounted to 3. i) CPT1 placed the slide tray on the benchtop with the red dot marking in the upper right corner. CPT1 loaded the slides onto the tray beginning in the upper right corner and continuing down towards self. CPT1 carried the slide tray to the PrepStain Processor and turned the tray 180 degrees in order to align with the positioning pin on the processor. The red dot marking was now located in the lower left corner closest to the user. j) There is no procedure for coverslipping, however CPT1 coverslipped slides when staining was complete. k) The procedure does not indicate how long specimens are stored. 3. Staff interview with CPT1 on 7/11/18 at 10:30 AM regarding the above preparation, processing and staining of GYN specimens confirmed the above findings. CPT1 stated: a) The order of preparing specimens for HPV does not matter. b) The procedure does not contain minimum quantities of reagents needed to process. c) Priming of PrepStain reagents before run is only done the first run of the day. d) Surepath tubes are saved for one month. B. Based on surveyor observation, record review and staff interview, the laboratory failed to have step by step specimen processing and staining procedures including slide preparation, reagents, stains, solutions and other materials used for SurePath urine specimens in the subspecialty of cytology. Findings include: 1. Surveyor observation on 7/11/18 at 11:00 AM of the accessioning, processing, staining of urine specimens using Surepath CytoRich Clear Preservative fluid as compared to the 'Protocol for Urine Preparation using SurePath Liquid Based Technology' procedure, revised 7/3/18 revealed CPT1

	either omitted, added or performed steps out of order as follows: a) The procedure does not indicate which centrifuge contains the program corresponding to the procedure in use. b) The Rotina centrifuge on the right contains programs 3 and 4 from the urine procedure. c) When the start button on the centrifuge is pressed, the program is called up. The start button must be hit a second time to start the centrifuge. d) Program 3 on the above Rotina 380 Centrifuge is a 10 minute spin. e) Contents of 50 ml conical tube are poured into the original container not the labeled SurePath centrifuge tube. f) 10 ml of CytoRich Clear Preservative was added to the 50 ml conical tube. g) Vortex 50 ml conical tube and pour into SurePath tube labeled accordingly with correct case #. h) Decant specimens into CytoRich waste container and blot. Place in SurePath tube rack with the rack # facing user. Place the tubes, beginning in the upper left corner and continue across to the right to complete all specimens. i) Specimens were vortexed for one second. j) Proper positioning of slides on staining rack and processing slides utilizing the PrepStain processor was observed but is omitted from the above procedure. 2. Staff interview with CPT1 on 7/11/18 at 11:22 AM, regarding the above processing and staining of urine Surepath specimens confirmed the above findings. CPT1 stated: a) If a urine cytology is received in no fixative, then the Surepath CytoRich Preservative is added by the laboratory. b) During nongyn urine training session with manufacturer representative, staff were told nongyn can be run utilizing the gynecological program and it was up to the laboratory to choose the program. c) The decision to run urine specimens together with gynecological specimens was made by pathologist #2. d) Surepath tubes and original urine containers are put in a storage rack and refrigerated for 1 week. e) During personnel competency assessment performed by CPT1, staff do not have the above procedure in hand. They refer to their individual notes.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure an approved written procedure was in place prior to performing urine cytology testing. Findings include: 1. Record review on 7/3/18 of the laboratory validation data sheet titled 'Validation of urine cytology slide prep via SurePath, November 20, 2015' revealed the validation data was not signed and dated by the laboratory director. 2. Record review on 7/20/18 of the 'CoPath Specimen Search' report revealed the first urine cytology specimen processed utilizing the Surepath CytoRich Clear Preservative was on 11/23/15. 3. Record review of the cytology procedures for urine on 7/3/18 revealed the following: a) The first documented written procedure, 'Urine Cytology Prep using SurePath' was signed and effective on 6/21/16 by the cytology technical supervisor. Documentation of approval by the laboratory director on 6/21/16 was not available. b) The first documentation of laboratory director approval was 11/17/17. 4. Staff interview with cytology prep technician #1 (CPT1) on 7/20/18 at 10:00 AM confirmed #2 above. CPT1 further stated: a) Handwritten notes from the training session for urine specimens with the manufacturer representative were initially utilized while a written procedure was being written. b) A manufacturer procedure was not available for use while a procedure was being written. 5. Staff interview on 7 /3/18 at 4:00 PM with the laboratory director confirmed the findings in #1 and #3 above.

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: Based on record review and staff interview, the laboratory failed to follow manufacturer instructions to ensure proper handling and prevent mix ups of cytology specimens utilizing the PrepStain Processor. Refer to D5203.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to ensure corrected reports were issued when an error is identified in the subspecialty of cytology. Findings include: 1. Staff interview with pathologist #2 (P2) on 7/3/18 at 10:17 AM revealed, 8 of 12 patients had their slides switched during slide preparation. This resulted in the switching of 8 samples, with an incorrect positive GYN smear for Patient #1 and an incorrect negative urine cytology result for Patient #2. 2. Record review on 7/3/18 of the final GYN cytology report on Patient #1 revealed a corrected report was not issued. 3. Record review on 7/3/18 of the final urine cytology report on Patient #2 revealed a corrected report was not issued. 4. Record review on 7/11/18 of the laboratory's, 'Quality Assurance Program for Gynecologic Cytology' procedure revealed, Section XIIIa Corrected Reports: "If there is a change in diagnosis an amended report will be issued stating reason for change in diagnosis." 5. Staff interview with P2 on 7/3/18 at 2:35 PM confirmed the above specimen mix up occurred on 7/10/17. P2 stated, "Corrected reports were not issued because the clinicians involved were notified and a subsequent urine was received on Patient #2 which was positive for malignant cells."
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 surveyor observation, record review and staff interview, the laboratory

	director failed to provide overall management and direction in accordance with 493. 1445. The cumulative effect of this lack of oversight resulted in the laboratory director's inability to ensure the accuracy and reliability of patient test results in the subspecialty of cytology. 1. The laboratory director failed to ensure technical supervisor duties were performed by qualified individuals. Refer to D6079. 2. The laboratory director failed to ensure testing systems developed and used by the laboratory provide quality services for all aspects of test performance. Refer to D6082. 3. The laboratory director failed to ensure testing personnel follow the procedure manual as written. Refer to D6087. 4. The laboratory director failed to 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. Refer to D6094. 5. The laboratory director failed to ensure all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. Refer to D6096. 6. The laboratory director failed to ensure that the general supervisor provides on-site supervision of high complexity test performance by testing personnel. Refer to D6100. 7. The laboratory director failed to ensure: a) Prior to testing patient specimens, all personnel receive the appropriate training and have demonstrated that they can perform all testing operations reliably. b) Identify training needs, needs for remedial training or continuing education to improve skills. Refer to D6102 and D6103. 8. The laboratory director failed to approve and sign new and/or revised cytology preparation procedures prior to patient testing. Refer to D6106.
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: Refer to D6121 and D6157.
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: Refer to D5203, D5393, D5407, D5411, D5821 and D6114.

D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Refer to D5203, D5311, D5403, D5411, D6118, D6120, and D6121.
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: Refer to D5203, D5313, D5393, and D5821.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified. This STANDARD is not met as evidenced by: Refer to D5393 and D6118.
D6100	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(10) The laboratory director must ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(4). This STANDARD is not met as evidenced by: Refer to D5209 and D6157.
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: Refer to D6120 and D6121.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Refer to D5203, D5393 and D6118
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Refer to D5407
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on record review and staff interview, the cytology technical supervisor (TS) failed to provide technical supervision of the laboratory in accordance with 493.1451. 1. The TS failed to ensure the test methodology used for processing GYN and urine cytology specimens was appropriate. Refer to D6114. 2. The TS failed to ensure remedial actions are taken whenever test systems deviate from the laboratory's established performance characteristics. Refer to D6118. 3. The TS failed to ensure testing personnel receive in-service training and education appropriate for the testing performed. Refer to D6120. 4. The TS failed to ensure competency assessment through direct observation of routine cytology specimen processing was performed by a qualified individual. Refer to D6121.
D6114	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(1) The technical supervisor is responsible for selection of the test methodology that is appropriate for the clinical use of the test results.

	This STANDARD is not met as evidenced by: Refer to D5203.
D6118	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(5) The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. This STANDARD is not met as evidenced by: Refer to D5393.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and staff interview, the technical supervisor failed to ensure cytology testing personnel were trained and had the skills and knowledge to perform urine SurePath cytology specimen processing prior to patient testing and after changes in testing. Findings include: 1. Record review on 7/20/18 of the CoPath Specimen Search report revealed, the first urine cytology specimen processed utilizing the Surepath CytoRich Clear Preservative was on 11/23/15. 2. Record review on 7/11/18 of the cytology training records revealed: a) A 'BD Attendance Roster, Program: Non GYN Training Urine' sheet dated 11/18/15 with verification of attendance for 3 of 5 cytology personnel employed at that time. b) Urine SurePath training records for 2 of 5 cytology personnel employed in 2015 were not available. c) Documentation of retraining when samples were switched during processing was not available. Refer to D5393. 3. Staff interview with cytology prep technician #1 (CPT1) on 7/11/18 at 4:00 PM confirmed the following: a) CPT1 attended the 11/18/15 training session. b) The above training attendance sheet was the only training document given by the manufacturer representative. c) A training checklist detailing what was covered at the training session was not available. 4. Staff interview with Pathologist #1 (P1) on 7/3/18 at 9:00 AM revealed, CPT1 performs the competency assessments on the staff performing urine and GYN specimen preparation, processing and staining.
D6121	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(i) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the technical supervisor (TS) failed to perform direct observation of SurePath specimen processing. Findings include: 1. Record review on 7/3/18 of the quality assurance (QA) minutes from 9/7/17 revealed "Everyone in cytology will be having competency review per the laboratory administrative manager (LM)." 2. Record review of the laboratory's competency records on 7/3/18 revealed: a) The documentation of direct observation by the TS was not available. b) Documentation of direct observation was performed by cytology prep technician #1 (CPT1) who is not qualified to be a TS. 3. Record review of CPT1's credentials on 7/3/18 revealed CPT1 has an associate's degree and does not qualify as a TS in the subspecialty of cytology. 4. Staff interview with CPT1 on 7/11/18 at 11:22 AM confirmed the above findings. Refer to D5403. 5. Staff interview with the LM on 7/3/18 at 3:00 PM revealed the following; a) CPT1 was responsible for the competency required in #1 above. b) LM defers to CPT1 in areas of Surepath GYN and urine specimen processing because CPT1 is the expert in specimen preparation and processing. 6. Staff interview with Pathologist #1 (P1) on 7/3/18 at 9:00 AM revealed: a) P1 is the CTS. b) CPT1 performs the competency assessments on the staff performing urine and GYN specimen preparation, processing and staining.
D6153	CYTOLOGY GENERAL SUPERVISOR CFR(s): 493.1467 For the subspecialty of cytology, the laboratory must have a general supervisor who meets the qualification requirements of 493.1469 of this subpart, and provides supervision in accordance with 493.1471 of this subpart. This CONDITION is not met as evidenced by: Refer to D6157
D6157	CYTOLOGY SUPERVISOR RESPONSIBILITIES CFR(s): 493.1471(a) The cytology general supervisor is responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. This STANDARD is not met as evidenced by: Based on record review and staff interview, the cytology general supervisor (CGS) failed to provide day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results. Findings include: 1. Record review on 7/3/18 of the laboratory's College of American Pathologists (CAP) 'Laboratory Personnel Evaluation Roster', signed by the laboratory director (LD) on 4/17/18, revealed, pathologist #1 (P1) was listed as the CGS. 2. Record review on 7/3/18 of the laboratory's 'Department of Pathology & Laboratory Medicine Organizational Chart' currently in use revealed P1 is listed as the section chief over cytology. 3. During staff interview with P1 on 7/3/18 at 9:00 AM, P1 stated: a) P1 was unaware he/she was listed as the CGS. b) P1 did not want to be the CGS. c) P1 thought the laboratory manager (LM) assumed the role of CGS when the previous CGS retired. d) P1 was not responsible for the day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results in

	cytology. e) P1 was unaware that urine and gynecological specimens were run together on the Surepath PrepStain instrument. f) P1 put a stop to the process once he /she became aware of it. g) Two weeks ago, it was brought to P1's attention that LM was not qualified to be the CGS. P1 printed out the Clinical Laboratory Improvement Amendment regulations for technical supervisor (TS) and CGS and brought them to Pathologist #2 (P2). 4. During staff interview with pathologist #2 (P2) on 7/3/18 at 10: 30 AM, P2 stated: a) P1 is the CGS but was never officially said as such. b) When the previous CGS retired, the decision was made not to have a cytology technologist in that role. c) The LM is the TS in cytology. d) P2 thought a general supervisor was more technical than a TS. e) P2 was unaware that signing new or changed procedures cannot be delegated by the laboratory director. 5. Staff interview with cytology technologist #1 (CT1) on 7/3/18 at 11:59 AM revealed, CT1 thought the CGS was the LM, however CT1 would go to the TS for technical issues. CT1 stated he/she was told to run the urine and GYN specimens together by cytology prep tech #1 (CPT1). 6. Staff interview with cytotechnologist #2 (CT2) on 7/3/18 at 10:20 AM revealed CT2 thought the CGS was the LM. CT2 stated, "LM has no knowledge of cytology and they are on their own." CT2 stated he/she was trained by CPT1 and cytology prep tech #2 to run urine and GYN specimens together. 7. Staff interview with cytology prep tech #3 (CPT3) on 7/3/18 at 12:30 PM revealed he/she was trained by CPT1 to run urine and GYN specimens together. CPT3 stated the LM is the cytology supervisor but CPT3 goes to cytology technologists or P1 if he/she has a problem.