Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0237590	04/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Novant Health Forsyth Medical	3333 Silas Creek Parkway, Winston-Salem, NC	

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
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 review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the laboratory failed to ensure written policies and procedures were followed to assess the competency of nine of nine Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The laboratory failed to follow the procedure COMPETENCY ASSESSMENT OF LABORATORY EMPLOYEES (NHLS) which stated: "C.2.c. Annually: After an individual has performed his or her duties for one year, competency will be assessed at least annually." "E.1.a.ii. Compilation of all applicable elements of competency onto the Competency Record Form must be completed within one month of the end of the competency period." 2. The Survey Team requested and the laboratory failed to provide documentation of competency assessments for nine of nine Technical Supervisors for 2019, 2020 and to the date of the survey in 2021. Technical Supervisors include: -Technical Supervisor A -Technical Supervisor B -Technical Supervisor C -Technical Supervisor D -Technical Supervisor E -Technical Supervisor F -Technical Supervisor G -Technical Supervisor H -Technical Supervisor I 3. During an interview on April 28, 2021 at 11:30 AM these findings were confirmed by the Laboratory Director/Technical Supervisor A and the Anatomic Pathology Manager.
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: Cross refer to D5473 Based on review of laboratory policies and procedures and interview it was determined that the laboratory failed to follow written policies and procedures to ensure stain assessment was performed for each stain process each day of use in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey team reviewed the procedure titled QUALITY MANAGEMENT PLAN FOR CYTOLOGY (NHLS) which stated: "C.4. Technical Quality and Stain Monitoring: Each day of staining, the cytotechnologists and/or pathologists review and assess the quality of each non-gyn stain." (see D5473) 2. During an interview on April 27, 2021 at 3:20 PM the Lead Cytotechnologist confirmed these findings.
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: A. Based on lack of laboratory records and interview it was determined that the laboratory failed to test Diff Quick staining materials for intended reactivity for four of four nongynecologic stain processes to ensure predictable staining characteristics for each day of use in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide stain assessment records for four of four nongynecologic stain processes for 2019, 2020 and to the date of the survey in 2021. Stain processes include: -"Cart #1" -"Cart #2" -"Cart #3" -"Cart #4" 2. During an interview on April 27, 2021 at 3:20 PM these findings were confirmed by the Lead Cytotechnologist. B. Based on lack of laboratory records and interview it was determined that the laboratory failed to test Papanicolaou staining materials for one of one nongynecologic stain process for intended reactivity to ensure predictable staining characteristics for each day of use in 2019, 2020 and to the date of the survey in 2021. Findings include: 1. The Survey Team requested and the laboratory failed to provide stain assessment records for one of one nongynecologic stain process for 2019, 2020 and to the date of the survey in 2021. Stain process includes: -"Manual Non-GYN Staining" 2. During an interview on April 27, 2021 at 3:20 PM these findings were confirmed by the Lead Cytotechnologist.
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: Based on review of laboratory policies and procedures, lack of laboratory records and interview it was determined that the Laboratory Director failed to ensure written policies and procedures were followed to assess, monitor and maintain the competency of nine of nine Technical Supervisors in 2019, 2020 and to the date of the survey in 2021. Cross refer to D5209
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.