Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	15D0360312	02/26/2020
Name of Provider or Supplier	**Street Address, City, State**	
Henry County Memorial Hospital Lab	1000 N 16th St Po Box 490, New Castle, IN	

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
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 review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to follow written policies and procedures to assess the competency of Technical Supervisors (refer to D5209); failed to establish written policies and procedures for one laboratory process (refer to D5403); failed to document testing of staining materials for intended reactivity (refer to D5473); failed to follow written policies and procedures for staining nongynecologic specimens that have a high potential for cross-contamination (refer to D5619); failed to establish written policies and procedures to maintain and annually evaluate required statistics (refer to D5629); failed to establish written policies and procedures for establishing, reassessing, and prorating workload limits for three of three Technical Supervisors (refer to D5633, D5637 and D5641); failed to establish written policies and procedures for documenting and maintaining workload records (refer to D5643 and D5645); failed to establish written policies and procedures to ensure that unsatisfactory nongynecologic slide preparations were identified and reported as unsatisfactory (refer to D5655); and failed to establish written policies and procedures to ensure reports contained narrative descriptive nomenclature (refer to D5657). 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.
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 interviews it was determined that the laboratory failed to follow written policies and procedures to assess the competency of three of three Technical Supervisors in 2018, 2019 and to the date of the survey in 2020. Findings include: 1. The laboratory failed to follow the procedure titled PATHOLOGIST PROFESSIONAL COMPETENCY which described how Technical Supervisor competency would be assessed based on the following activities: - Peer review concordance - Continuing education activities - Annual quality assurance evaluations 2. The Survey Team requested and the laboratory failed to provide records of competency assessment for three of three Technical Supervisors who performed microscopic evaluations in 2018, 2019 and to the date of the survey in 2020. Technical Supervisors include: - Laboratory Director /Technical Supervisor A - Technical Supervisor B - Technical Supervisor C 3. During an interview on 2/25/20 at 10:40 AM, Laboratory Director/Technical Supervisor A confirmed that there were no records of competency assessment for the Technical Supervisors. 4. During an interview on 2/26/20 at 11:15 AM, Laboratory Director /Technical Supervisor A and the Operations Director confirmed these findings.
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 41 laboratory policies and procedures and interviews it was determined that the laboratory failed to establish written policies and procedures for one laboratory process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's system for entering results in the patient record and reporting patient results. 2. During an interview on 2/25/20 at 1:45 PM, Histotechnician A confirmed

	that there were no procedures for entering and reporting patient results in the laboratory's information system and that "the pathologist just dictates right into the record." 3. During an interview on 2/26/20 at 11:15 AM, Laboratory Director /Technical Supervisor A and the Operations Director 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: Based on review of laboratory records and interviews it was determined that the laboratory failed to test staining materials for intended reactivity to ensure predictable staining characteristics for two of two stain processes each day of use in October through December 2019. Findings include: 1. The Survey Team reviewed laboratory records titled DAILY REVIEW OF HISTOLOGY PREPARATIONS from October through December 2019. a. The laboratory failed to document the staining characteristics of Diff-Quik stain processes on 13 of 13 days of use. Dates include: - 10/3/19 - 10/8/19 - 10/10/19 - 10/22/19 - 10/23/19 - 11/8/19 - 11/11/19 - 11/14/19 - 11/21/19 - 11/22/19 - 11/27/19 - 12/5/19 - 12/12/19 b. The laboratory failed to document the staining characteristics of Papanicoloau stain processes on 13 of 13 days of use. Dates include: - 10/3/19 - 10/8/19 - 10/10/19 - 10/22/19 - 10/23/19 - 11/8/19 - 11/11/19 - 11/14/19 - 11/21/19 - 11/22/19 - 11/27/19 - 12/5/19 - 12/12/19 2. During an interview on 2/25/20 at 9:15 AM, Histotechnician A confirmed that laboratory records failed to document the staining characteristics of Diff-Quik and Papanicoloau stain processes. 3. During an interview on 2/25/20 at 10:40 AM, Laboratory Director /Technical Supervisor A confirmed that laboratory records failed to document the staining characteristics of Diff-Quik and Papanicoloau stain processes. 4. During an interview on 2/26/20 at 11:15 AM, Laboratory Director/Technical Supervisor A and the Operations Director confirmed these findings.
D5619	CYTOLOGY CFR(s): 493.1274(b)(3) (b) Staining. The laboratory must have available and follow written policies and procedures for each of the following, if applicable: (b)(3) Nongynecologic specimens that have a high potential for cross-contamination must be stained separately from other nongynecologic specimens, and the stains must be filtered or changed following staining. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to follow written policies and procedures to prevent cross-contamination during Papanicolaou staining of nongynecologic specimens that have a high potential for cross-contamination. Findings include: 1. The laboratory failed to follow the procedure titled NON-GYN CYTOLOGY STAIN which stated: "A blank control slide will be run with each

	staining to check for contamination. This latter check will be recorded on the pathologist's daily review sheet." 2. The Survey Team reviewed laboratory records titled DAILY REVIEW OF HISTOLOGY PREPARATIONS from October through December 2019. a. The laboratory failed to document the outcome of the blank control slide review on 13 of 13 days when Papanicolaou staining of nongynecologic specimens occurred. Dates include: - 10/3/19 - 10/8/19 - 10/10/19 - 10/22/19 - 10/23 /19 - 11/8/19 - 11/11/19 - 11/14/19 - 11/21/19 - 11/22/19 - 11/27/19 - 12/5/19 - 12/12 /19 3. During an interview on 2/25/20 at 9:15 AM, Histotechnician A confirmed that laboratory records failed to document the blank slide review. 4. During an interview on 2/25/20 at 10:40 AM, Laboratory Director/Technical Supervisor A confirmed that laboratory records failed to document the blank slide review. 5. During an interview on 2/26/20 at 11:15 AM, Laboratory Director/Technical Supervisor A and the Operations Director confirmed these findings.
D5629	CYTOLOGY CFR(s): 493.1274(c)(5) (c) Control procedures. The laboratory must establish and follow written policies and procedures for a program designed to detect errors in the performance of cytologic examinations and the reporting of results. The program must include the following: (c)(5) An annual statistical laboratory evaluation of the number of - (c)(5)(i) Cytology cases examined; (c)(5)(ii) Specimens processed by specimen type; (c)(5)(iii) Patient cases reported by diagnosis (including the number reported as unsatisfactory for diagnostic interpretation); (c)(5)(iv) Gynecologic cases with a diagnosis of HSIL, adenocarcinoma, or other malignant neoplasm for which histology results were available for comparison; (c)(5)(v) Gynecologic cases where cytology and histology are discrepant; and (c)(5)(vi) Gynecologic cases where any rescreen of a normal or negative specimen results in reclassification as low-grade squamous intraepithelial lesion (LSIL), HSIL, adenocarcinoma, or other malignant neoplasms. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures for the evaluation and comparison of three of three laboratory statistics, and failed to document one of three required annual statistics for 2018 and 2019. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an annual statistical evaluation of three required laboratory statistics for nongynecologic specimens. 2. The Survey Team requested and the laboratory failed to provide documentation for the number of nongynecologic cytology cases reported by diagnosis in 2018 and 2019. 3. During an interview on 2/25 /20 at 9:15 AM, Histotechnician A stated that the laboratory did not have a process for tracking the number of nongynecologic cytology cases reported by diagnosis. 4. During an interview on 2/25/20 at 10:40 AM, Laboratory Director/Technical Supervisor A confirmed that there were no procedures for evaluation of annual laboratory statistics. 5. During an interview on 2/26/20 at 11:15 AM, Laboratory Director/Technical Supervisor A and the Operations Director confirmed these findings.
D5633	CYTOLOGY CFR(s): 493.1274(d)(1) (d) Workload limits. The laboratory must establish and follow written policies and

	procedures that ensure the following: (d)(1) The technical supervisor establishes a maximum workload limit for each individual who performs primary screening. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that a maximum workload limit was established by the Laboratory Director/Technical Supervisor A for three of three Technical Supervisors in 2018, 2019 and to the date of the survey in 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures stating that individual maximum workload limits were established for each Technical Supervisor that performed primary screening of cytology specimens. 2. The Survey Team requested and the laboratory failed to provide documentation to show that individual maximum workload limits were established for three of three Technical Supervisors in 2018, 2019 and to the date of the survey in 2020. Technical Supervisors include: - Laboratory Director/Technical Supervisor A - Technical Supervisor B - Technical Supervisor C 3. During an interview on 2/25/20 at 10:40 AM, Laboratory Director/Technical Supervisor A confirmed that there were no procedures for establishing and documenting individual maximum workload limits for the Technical Supervisors. 4. During an interview on 2/26/20 at 11:15 AM, Laboratory Director/Technical Supervisor A and the Operations Director confirmed these findings.
D5637	CYTOLOGY CFR(s): 493.1274(d)(1)(ii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(1)(ii) Each individual's workload limit is reassessed at least every 6 months and adjusted when necessary. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, lack of laboratory records and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that the workload limits for three of three Technical Supervisors were reassessed at least every six months and adjusted when necessary in 2018, 2019 and to the date of the survey in 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the reassessment of workload limits at least every six months for three of three Technical Supervisors. 2. The Survey Team requested and the laboratory failed to provide documentation of a reassessed workload limit for three of three Technical Supervisors in 2018, 2019 and to the date of the survey in 2020. Technical Supervisors include: - Laboratory Director/Technical Supervisor A - Technical Supervisor B - Technical Supervisor C 3. During an interview on 2/25/20 at 10:40 AM, Laboratory Director /Technical Supervisor A confirmed that there were no procedures for reassessing workload limits for the Technical Supervisors every six months. 4. During an interview on 2/26/20 at 11:15 AM, Laboratory Director/Technical Supervisor A and the Operations Director confirmed these findings.
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii)

	(d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined; This STANDARD is not met as evidenced by: Based on 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 workload limit for three of three Technical Supervisors, when examining slides in less than an 8-hour workday and with duties other than slide examination, would be prorated using a period of eight hours to determine the number of slides that may be examined. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to determine how to prorate the workload limit for Technical Supervisors. 2. During an interview on 2/25 /20 at 10:40 AM, Laboratory Director/Technical Supervisor A confirmed that there were no procedures to ensure daily workload limits would be prorated. 3. During an interview on 2/26/20 at 11:15 AM, Laboratory Director/Technical Supervisor A and the Operations Director confirmed these findings.
D5643	CYTOLOGY CFR(s): 493.1274(d)(2)(iii) (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: (d)(2)(iii) Nongynecologic slide preparations made using liquid-based slide preparatory techniques that result in cell dispersion over one-half or less of the total available slide may be counted as one-half slide; and (d)(2) (iv) Technical supervisors who perform primary screening are not required to include tissue pathology slides and previously examined cytology slides (gynecologic and nongynecologic) in the 100 slide workload limit. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interviews it was determined that the laboratory failed to establish written policies and procedures to designate how nongynecologic slide preparations were counted for workload recording purposes. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's process for counting nongynecologic slide preparations with cell dispersion over one-half or less of slide (cytospin) for the purpose of documenting workload. 2. During an interview on 2/25/20 at 10:40 AM, Laboratory Director /Technical Supervisor A confirmed that there were no procedures to designate how slide preparations would be counted for workload recording. 3. During an interview on 2/26/20 at 11:15 AM, Laboratory Director/Technical Supervisor A and the Operations Director confirmed these findings.
D5645	CYTOLOGY CFR(s): 493.1274(d)(3) (d) Workload limits. The laboratory must establish and follow written policies and

	procedures that ensure the following: (d)(3) The laboratory must maintain records of the total number of slides examined by each individual during each 24-hour period and the number of hours spent examining slides in the 24-hour period irrespective of the site or laboratory. This STANDARD is not met as evidenced by: Based on 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 laboratory would maintain records of the total number of slides examined and the number of hours spent examining slides during each 24-hour period. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the laboratory maintained workload records to document the total number of slides examined and time spent examining slides during each 24-hour period. 2. During an interview on 2/25/20 at 10:40 AM, Laboratory Director/Technical Supervisor A confirmed that there were no procedures to ensure the maintenance of workload records. 3. During an interview on 2/26/20 at 11:15 AM, Laboratory Director/Technical Supervisor A and the Operations Director confirmed these findings.
D5655	CYTOLOGY CFR(s): 493.1274(e)(4) (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following: (e)(4) Unsatisfactory specimens or slide preparations are identified and reported as unsatisfactory. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure that unsatisfactory nongynecologic slide preparations were identified and reported as unsatisfactory. The Laboratory failed to identify and report one of six nongynecologic cytology cases from January 2018 through February 2020 as being "Unsatisfactory for Evaluation." Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the requirements for an adequate nongynecologic slide preparations. 2. The Laboratory failed to identify and report one nongynecologic cytology case as being "Unsatisfactory for Evaluation." Case includes: - 22-NG-18-23 3. During an interview on 2/25/20 at 10:40 AM, Laboratory Director/Technical Supervisor A confirmed that there were no procedures for identifying and reporting unsatisfactory cytology preparations. 4. During an interview on 2/26/20 at 11:15 AM, Laboratory Director /Technical Supervisor A and the Operations Director confirmed these findings.
D5657	CYTOLOGY CFR(s): 493.1274(e)(5) (e) The laboratory must establish and follow written policies and procedures that ensure the following: (e)(5) The report contains narrative descriptive nomenclature for all results. This STANDARD is not met as evidenced by:

	Based on review of laboratory policies and procedures and interviews it was determined that the laboratory failed to establish written policies and procedures to ensure nongynecologic test reports contained narrative descriptive nomenclature. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the laboratory's nomenclature system for reporting nongynecologic test results. 2. During an interview on 2/25/20 at 10:40 AM, Laboratory Director/Technical Supervisor A confirmed that there were no procedures for reporting nongynecologic tests with narrative descriptive nomenclature. 3. During an interview on 2/26/20 at 11:15 AM, Laboratory Director/Technical Supervisor A and the Operations Director confirmed these findings.
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, laboratory records 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 D5209, D5403, D5473, D5619, D5629, D5633, D5637, D5641, D5643, D5645, D5655, and D5657
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 the review of laboratory policies and procedures, laboratory records and interviews it was determined that the Laboratory Director failed to ensure written policies and procedures were established to assess the competency of two of two Histotechnicians who accessioned and processed cytology specimens in 2018, 2019 and to the date of the survey in 2020. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to determine how cytology accessioning and cytopreparatory competency was assessed for laboratory

	staff. 2. The Survey Team reviewed laboratory records titled HISTOLOGY COMPETENCY FORM for two of two Histotechnicians who performed cytology accessioning and processing in 2018 and 2019. Histotechnicians include: - Histotechnician A - Histotechnician B a. During an interview on 2/25/20 at 10:40 AM, Laboratory Director/Technical Supervisor A confirmed that there were no procedures for how the Histotechnician competency forms were completed and competency was assessed. 3. During an interview on 2/26/20 at 11:15 AM, Laboratory Director/Technical Supervisor A and the Operations Director confirmed these findings.
D6130	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(2)(3) (c) In cytology, the technical supervisor or the individual qualified under 493.1449(k)(2)-- (c)(2) Must establish the workload limit for each individual examining slides and (c)(3) Must reassess the workload limit for each individual examining slides at least every 6 months and adjust as necessary. This STANDARD is not met as evidenced by: Based on review of laboratory records and interviews it was determined that the Technical Supervisor failed to establish individual workload limits and reassess the workload limits at least every six months for three of three Technical Supervisors performing primary slide examinations in 2018, 2019 and to the date of the survey in 2020. Cross refer to D5633 and D5637
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.