

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2007462	(X3) Date Survey Completed 02/26/2025
Name of Provider or Supplier Cpa-Baptist North Central	Street Address, City, State 520 Madison Oak Dr, San Antonio, TX	
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	<p>CYTOLOGY CFR(s): 493.1221</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to establish written policies and procedures for an annual statistical evaluation of the required laboratory statistics (refer to D5629); failed to establish and follow written policies and procedures for the establishment, reassessment and documentation of individual workload limits (refer to D5633, D5637 and D5647); failed to establish written policies and procedures to ensure that workload limits would be prorated when examining slides in less than eight hours (refer to D5641); failed to establish and follow written policies and procedures to ensure the laboratory maintained records of the total number of slides examined and the total number of hours spent examining slides per 24-hour period (refer to D5645); failed to establish written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory (refer to D5655); failed to establish and follow written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results (refer to D5657); failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the analytic cytology systems (refer to D5791); and failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic cytology systems (refer to D5891).</p>
D5401	PROCEDURE MANUAL

CFR(s): 493.1251(a)

(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 review of 15 laboratory policies and procedures, laboratory records and interview with Technical Supervisor B the laboratory failed to follow one written policy and procedure. Findings include: 1. The laboratory failed to follow the procedure MICROSCOPIC EXAMINATION OF ANATOMIC PATHOLOGY SPECIMENS, which stated: "The pathologist will review the staining and slide quality each day as well as the quality of the gross. The results of this review are recorded on the CPA Daily Histology and Cytology QA Log." 2. The Survey Team reviewed records titled SURGICAL AND CYTOLOGY STAIN QUALITY LOG from January 2024 through December 2024. The laboratory failed to document the stain quality for 19 of 26 days. Dates include: -01/16/24 -01/19/24 -02/05/24 -02/19/24 -02/25/24 -02/28/24 -02/29/24 -03/04/24 -03/07/24 -03/11/24 -03/19/24 -04/01/24 -04/15/24 -04/18/24 -05/06/24 -05/13/24 -05/23/24 -07/02/24 -11/20/24 3. During an interview on February 24, 2025 at 1:15 PM, these findings were confirmed with Technical Supervisor B.

D5403

PROCEDURE MANUAL

CFR(s): 493.1251(b)

(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 15 laboratory policies and procedures and interview with Technical Supervisor B the laboratory failed to establish written policies and procedures for one laboratory test process. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to describe the step-by-step process for reporting nongynecologic cytology test results

into the laboratory information system (LIS). 2. During an interview on February 24, 2025 at 10:20 AM, these findings were confirmed with Technical Supervisor B.

D5629

CYTOLOGY
CFR(s): 493.1274(c)(5)

(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 and interview with Technical Supervisor B the laboratory failed to establish written policies and procedures for the evaluation and comparison of three of three nongynecologic cytology statistics. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for the evaluation and comparison of three of three nongynecologic cytology statistics. Statistics include: -Number of nongynecologic cytology cases examined -Number of nongynecologic specimens processed by specimen type -Number of nongynecologic cases reported by diagnosis, including the number reported as unsatisfactory 2. During an interview on February 24, 2025 at 10: 20 AM, these findings were confirmed with Technical Supervisor B.

D5633

CYTOLOGY
CFR(s): 493.1274(d)(1)

(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 and interview with Technical Supervisor B the laboratory failed to establish written policies and procedures to establish an individual maximum workload limit for each Technical Supervisor who performed primary screening of cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor would establish maximum workload limits for each Technical Supervisor who performed primary screening of cytology specimens. 2. During an interview on February 24, 2025 at 10:20 AM, these findings were confirmed with Technical Supervisor B.

D5637

CYTOLOGY
CFR(s): 493.1274(d)(1)(ii)

(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, workload limit reassessment records and interviews with Technical Supervisor B the laboratory failed to establish and follow written policies and procedures to reassess and adjust when necessary, a maximum workload limit at least every six months for the Technical Supervisors who performed primary screening of cytology specimens. The Technical Supervisor failed to reassess a maximum workload limit for seven of seven Technical Supervisors at least every six months in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to detail how the Technical Supervisor would reassess a maximum workload limit for the Technical Supervisors at least every six months and adjust when necessary. 2. The Survey Team reviewed workload limit reassessment records titled PATHOLOGIST CYTOLOGY WORKLOAD LIMIT DESIGNATION for 2023, 2024 and January 1, 2025 to the date of the survey in 2025. The Technical Supervisor failed to reassess the workload limits at least every six months for seven of seven Technical Supervisors. Technical Supervisors include: - Technical Supervisor A reassessment approval dates: 03/08/23 (effective date on record 12/28/22) 08/15/23 (effective date on record 08/15/23) 08/08/24 (effective date on record 04/01/24) 01/16/25 (effective date on record 01/07/25) -Technical Supervisor B reassessment approval dates: 03/08/23 (effective date on record 12/28/22) 08/15/23 (effective date on record 08/15/23) 08/08/24 (effective date on record 04/01/24) 01/16/25 (effective date on record 01/07/25) -Technical Supervisor C reassessment approval dates: 03/08/23 (effective date on record 12/28/22) 08/15/23 (effective date on record 08/15/23) 08/08/24 (effective date on record 04/01/24) 01/16/25 (effective date on record 01/07/25) -Technical Supervisor D reassessment approval dates: 03/08/23 (effective date on record 12/28/22) 08/15/23 (effective date on record 08/15/23) 08/08/24 (effective date on record 04/01/24) 01/16/25 (effective date on record 01/07/25) -Technical Supervisor E reassessment approval dates: 08/15/23 (effective date on record 08/15/23) 08/08/24 (effective date on record 04/01/24) 01/16/25 (effective date on record 01/07/25) -Technical Supervisor F reassessment approval dates: 03/08/23 (effective date on record 12/28/22) 08/15/23 (effective date on record 08/15/23) 08/08/24 (effective date on record 04/01/24) 01/16/25 (effective date on record 01/07/25) -Technical Supervisor G reassessment approval dates: 08/02/23 (effective date on record 08/01/23) 08/08/24 (effective date on record 04/01/24) 01/16/25 (effective date on record 01/07/25) a. The laboratory failed to specify if the workload reassessment began on the approval date or the effective date. 3. During interviews on February 24, 2025 at 10:20 AM and 1:15 PM, these findings were confirmed with Technical Supervisor B.

D5641

CYTOLOGY
 CFR(s): 493.1274(d)(2)(ii)

(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 interview with Technical

Supervisor B the laboratory failed to establish written policies and procedures to ensure workload limits for the Technical Supervisors would be prorated when examining slides in less than an eight-hour work day. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to prorate workload limits for the Technical Supervisors when examining slides in less than an eight-hour day, or with duties other than examining cytology specimen slides. 2. During an interview on February 24, 2025 at 10:20 AM, these findings were confirmed with Technical Supervisor B.

D5643

CYTOLOGY
CFR(s): 493.1274(d)(2)(iii)

(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 interview with Technical Supervisor B the laboratory failed to establish written policies and procedures to designate how nongynecologic Hologic ThinPrep slide preparations, cytospin preparations and cell block 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 designate how nongynecologic Hologic ThinPrep slide preparations, cytospin preparations and cell block preparations (cell dispersion over one-half or less of slide) were counted for workload recording. 2. During an interview on February 25, 2025 at 8:50 AM, Technical Supervisor B stated nongynecologic Hologic ThinPrep slide preparations, cytospin preparations and cell block preparations were counted as one-half slide for workload recording.

D5645

CYTOLOGY
CFR(s): 493.1274(d)(3)

(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, workload records and interviews with Technical Supervisor B the laboratory failed to establish and follow written policies and procedures to ensure the laboratory maintained records of the total number of slides examined by each individual per 24-hour period and the number of hours individuals spent examining slides per 24-hour period. Six of seven Technical Supervisors failed to maintain records of the total number of slides examined and number of hours spent examining slides per 24-hour period in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure the laboratory maintained records of the total number of slides examined by each individual per 24-hour period and the number of hours individuals spent examining slides per 24-hour period. 2. The Survey

Team reviewed records titled CYTOLOGY WORKLOAD REVIEW LOG for 2024. The Technical Supervisors documented each case screened, the number slides examined and the number of hours spent examining each case on the records. The records included cases the Technical Supervisors reviewed at other laboratories. a. The Laboratory Director/Technical Supervisor A failed to document the number of slides screened and the number of hours spent examining two cases. Date Case screened -03/12/24 SANG24-000096 -06/18/24 SANG24-000202 b. Technical Supervisor B failed to document the number of slides screened and the number of hours spent examining two cases. Date Case screened -01/16/24 SANG24-000012 -01/16/24 SANG24-000015 c. Technical Supervisor C failed to document the number of slides screened and the number of hours spent examining one case. Date Case screened -05/06/24 SANG24-000163 d. Technical Supervisor E failed to document the number of slides screened and the number of hours spent examining two cases. Date Case screened -03/19/24 SANG24-000105 -07/02/24 SANG24-000203 e. Technical Supervisor F failed to document the number of slides screened and the number of hours spent examining two cases. Date Case screened -02/28/24 SANG24-000073 -02/29/24 SANG24-000071 f. Technical Supervisor G failed to document the number of slides screened and the number of hours spent examining five cases. Date Case screened -02/25/24 SANG24-000068 -04/15/24 SANG24-000137 -04/18/24 SANG24-000140 -05/23/24 SANG24-000177 -11/20/24 SANG24-000221 3. During an interview on February 24, 2025 at 10:20 AM, Technical Supervisor B stated "there was some confusion on how to record the Baptist cases." 4. During an interview on February 24, 2025 at 1:15 PM, these findings were confirmed with Technical Supervisor B.

D5647

CYTOLOGY
CFR(s): 493.1274(d)(4)

(d)(4) Records are available to document the workload limit for each individual. (e) Slide examination and reporting. The laboratory must establish and follow written policies and procedures that ensure the following:

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures and interview with Technical Supervisor B the laboratory failed to establish written policies and procedures to ensure records were available to document the workload limit for the Technical Supervisors who performed primary screening of cytology specimens. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure records were available to document the workload limit for the Technical Supervisors who performed primary screening of cytology specimens. 2. During an interview on February 24, 2025 at 10:20 AM, these findings were confirmed with Technical Supervisor B.

D5655

CYTOLOGY
CFR(s): 493.1274(e)(4)

(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 interview with Technical

Supervisor B the laboratory failed to establish written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to ensure unsatisfactory nongynecologic cytology slide preparations were identified and reported as unsatisfactory. 2. During an interview on February 24, 2025 at 10:20 AM, these findings were confirmed with Technical Supervisor B.

D5657

CYTOLOGY
CFR(s): 493.1274(e)(5)

(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 interview with Technical Supervisor B the laboratory failed to establish and follow written policies and procedures for the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to define the criteria used and the system of narrative descriptive nomenclature used by the laboratory to report nongynecologic cytology test results. 2. During an interview on February 24, 2025 at 10:20 AM, these findings were confirmed with Technical Supervisor B.

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.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, lack of quality assessment records and interviews with Technical Supervisor B the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the analytic cytology systems. The laboratory failed to document analytic quality assessment activities during 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing program to monitor, assess and correct problems identified in the analytic cytology systems. 2. The Survey Team requested and the laboratory failed to provide documentation of analytic quality assessment activities during 2023, 2024 and January 1, 2025 to the date of the survey in 2025. a. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate the annual statistical evaluation of the required laboratory statistics. Refer to D5629 b. The Survey Team requested and the laboratory failed to provide written policies and procedures for a mechanism to monitor and evaluate the reassessment of workload limits. Refer to D5637 and D5647 c. The Survey Team requested and the laboratory failed to provide written policies and procedures for a

mechanism to monitor and evaluate workload records. Refer to D5645 3. During interviews on February 24, 2025 at 10:20 AM and 1:15 PM, these findings were confirmed with Technical Supervisor B.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

(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 postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on review of laboratory policies and procedures, laboratory records and interviews with Technical Supervisor B the laboratory failed to establish written policies and procedures for an ongoing mechanism to monitor, assess and correct problems in the postanalytic phases of cytology testing by monitoring the accuracy of final test reports. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for an ongoing mechanism to monitor, assess and correct problems identified in the postanalytic phases of testing by monitoring the accuracy of final test reports. 2. The Survey Team compared 33 final test reports with the corresponding test requisitions and specimen slides from December 2023 through December 2024. Nine of 33 final test reports contained errors. Final test reports include: Final test report #1: -SANG24-000012 A Test report: 7 fixed slides, 5 air-dried slides, 1 touch prep slide Actual glass slides: 6 fixed slides, 6 air-dried slides, 1 Hologic ThinPrep slide Final test report #2: -SANG24-000015 A Test report: 1 touch prep slide Actual glass slides: 1 Hologic ThinPrep slide - SANG24-000015 B Test report: 1 touch prep slide Actual glass slides: 1 Hologic ThinPrep slide Final test report #3: -SANG24-000021 A Test report: 1 touch prep slide Actual glass slides: 1 Hologic ThinPrep slide -SANG24-000021 B Test report: 1 touch prep slide Actual glass slides: 1 Hologic ThinPrep slide Final test report #4 - SANG24-000022 A Test report: 1 touch prep slide Actual glass slides: 1 Hologic ThinPrep slide Final test report #5: -SANG24-000023 A Test report: 1 touch prep slide Actual glass slides: 1 Hologic ThinPrep slide Final test report #6: -SANG24-000088 A Test report: 3 H&E cell block slides Actual glass slides: 6 H&E cell block slides Final test report #7: -SANG24-000105 A Test report: 2 H&E cell block slides Actual glass slides: 3 H&E cell block slides Final test report #8: -SANG24-000177 A Test report: 3 fixed slides, 9 air-dried slides Actual glass slides: 9 fixed slides, 3 air-dried slides Final test report #9: -SANG24-000190 A Test report: 6 fixed slides, 5 air-dried slides Actual glass slides: 6 fixed slides, 4 air-dried slides 3. During interviews on February 24, 2025 at 10:20 AM and 1:15 PM, these findings were confirmed with Technical Supervisor B.

D6130

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(c)(2)(3)

(c)(2) Must establish the workload limit for each individual examining slides; (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 workload limit records and interviews with Technical Supervisor

	<p>B the Technical Supervisor failed to reassess a maximum workload limit at least every six months for seven of seven Technical Supervisors in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Findings include: 1. The Technical Supervisor failed to reassess a maximum workload limit for seven of seven Technical Supervisors at least every six months in 2023, 2024 and January 1, 2025 to the date of the survey in 2025. Refer to D5637</p>
<p>D6133</p>	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(c)(6)</p> <p>(c)(6) If responsible for screening cytology slide preparations, must document the number of cytology slides screened in 24 hours and the number of hours devoted during each 24-hour period to screening cytology slides.</p> <p>This STANDARD is not met as evidenced by: Based on review of workload records and interviews with Technical Supervisor B six of seven Technical Supervisors failed to document the number of cytology slides screened in 24 hours and the number of hours devoted to screening cytology slides during each 24-hour period in 2024. Findings include: 1. Six of seven Technical Supervisors failed to maintain records of the total number of slides examined and number of hours devoted to examining cytology slides per 24-hour period in 2024. Refer to D5645</p>
<p>D9999</p>	<p>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.</p>