

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0685109	(X3) Date Survey Completed 10/23/2024
Name of Provider or Supplier High Point Regional Health	Street Address, City, State 222 W. Ray Avenue, High Point, 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
D2000	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on interviews and review of annual gynecologic cytology proficiency test (PT) records Facility B (CLIA #34D0685109) referred gynecologic cytology PT slidesets to Facility A (CLIA #34D0238170) in 2022 and 2023. (Refer to D2013)</p>
D2013	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(4)</p> <p>The laboratory must not send proficiency testing samples or portions of proficiency testing samples to another laboratory for any analysis for which it is certified to perform in its own laboratory. Any laboratory that CMS determines intentionally referred a proficiency testing sample to another laboratory for analysis may have its certification revoked for at least one year. If CMS determines that a proficiency testing sample was referred to another laboratory for analysis, but the requested testing was limited to reflex, distributive, or confirmatory testing that, if the sample were a patient specimen, would have been in full conformance with written, legally accurate and adequate standard operating procedures for the laboratory's testing of patient specimens, and if the proficiency testing referral is not a repeat proficiency</p>

testing referral, CMS will consider the referral to be improper and subject to alternative sanctions in accordance with 493.1804(c), but not intentional. Any laboratory that receives a proficiency testing sample from another laboratory for testing must notify CMS of the receipt of that sample regardless of whether the referral was made for reflex or confirmatory testing, or any other reason.

This STANDARD is not met as evidenced by:

Based on interviews and review of annual gynecologic cytology PT records the laboratory (Facility B) referred one annual gynecologic cytology Proficiency Test (PT) slideset consisting of 10 slides to Facility A in 2022. The laboratory (Facility B) referred two annual gynecologic cytology PT slidesets consisting of 10 slides each to Facility A in 2023. Findings include: 1. During interviews on October 21, 2024 these findings were confirmed by Proctor B, Cytotechnologist A and Laboratory Director /Technical Supervisor A. a. At 3:22 PM, Proctor B stated that Proctor A delivered the annual gynecologic cytology PT slidesets to Facility A in 2022 and 2023 and administered the test to three of three Technical Supervisors in their offices. Proctor B stated that the Technical Supervisors never came to Facility B to participate in the annual gynecologic cytology PT event. Proctor B also stated that Proctor A was no longer employed at Facility A or Facility B. b. At 3:31 PM, Cytotechnologist A confirmed that the annual gynecologic cytology PT slidesets were delivered to Facility A in 2022 and 2023 and that testing was administered to three of three Technical Supervisors in their offices. Cytotechnologist A stated that, beginning with the 2024 gynecologic cytology PT event due soon, the Technical Supervisors will be required to come to Facility B to take the test. c. At 4:48 PM, Laboratory Director /Technical Supervisor A confirmed during a phone interview that Technical Supervisor A, Technical Supervisor B, and Technical Supervisor C received annual gynecologic cytology PT slidesets from Facility B and completed the testing event in their offices at Facility A in 2022 and 2023. 2. The Survey Team reviewed annual gynecologic cytology PT records from 2022 for Technical Supervisor A, Technical Supervisor B and Technical Supervisor C. While the gynecologic cytology PT records stated the CLIA number for the PT event was for Facility B, three of three Technical Supervisors performed the PT testing event at Facility A in 2022. a. Technical Supervisor A tested on the 10-slide testing set #34278 on 10/17/2022. b. Technical Supervisor B tested on the 10-slide testing set #34278 on 10/17/2022. c. Technical Supervisor C tested on the 10-slide testing set #34278 on 10/17/2022. 3. The Survey Team reviewed annual gynecologic cytology PT records from 2023 for Technical Supervisor A, Technical Supervisor B and Technical Supervisor C. While the gynecologic cytology PT records stated the CLIA number for the PT event was for Facility B, three of three Technical Supervisors performed the PT testing event at Facility A in 2023. a. Technical Supervisor A tested on the 10-slide testing set #34137 on 08/21/2023. b. Technical Supervisor B tested on the 10-slide testing set #34136 on 08/21/2023. c. Technical Supervisor C tested on the 10-slide testing set #34136 on 08/21/2023.

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 22 laboratory policies and procedures and interview the laboratory procedure manual failed to include 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 detail the process for reprocessing gynecologic cytology specimens with glacial acetic acid.. 2. During an interview on October 23, 2024 at 1:18 PM Cytotechnologist A confirmed these findings.

D5631

CYTOLOGY
 CFR(s): 493.1274(c)(6)

(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) (6) An evaluation of the case reviews of each individual examining slides against the laboratory's overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, corrective actions taken.

This STANDARD is not met as evidenced by:
 Based on review of laboratory policies and procedures, lack of laboratory records and interview the laboratory failed to establish and follow written policies and procedures for a program to evaluate the gynecologic cytology case reviews of two of two Cytotechnologists against the laboratory's overall statistical values in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures for a program to evaluate the gynecologic cytology case reviews of Cytotechnologists against the laboratory's overall statistical values. 2. The Survey Team requested and the laboratory failed to provide records documenting the evaluation of gynecologic cytology case reviews of two of two Cytotechnologists against the laboratory's overall statistical values in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B 3. During an interview on October 22, 2024 at 11:58 AM Cytotechnologist A confirmed these findings stating that the records provided evaluated the gynecologic cytology case reviews of Cytotechnologist A against the gynecologic cytology case reviews of Cytotechnologist B and did not include the laboratory's overall statistical values.

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 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 Cytotechnologists. The laboratory failed to provide records of a reassessed maximum workload limit for two of two Cytotechnologists in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Survey Team requested and the laboratory failed to provide written policies and procedures to reassess and adjust when necessary a maximum workload limit at least every six months for the Cytotechnologists. 2. The Survey Team requested and the laboratory failed to provide records of a reassessed maximum workload limit for two of two Cytotechnologists in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Cytotechnologists include: -Cytotechnologist A -Cytotechnologist B 3. During an interview on October 22, 2024 at 11:58 AM Cytotechnologist A confirmed these findings. 4. During an interview on October 23, 2024 at 2:30 PM Anatomic Pathology Manager confirmed these findings.

D5805

TEST REPORT

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of final test reports and interview 155 of 155 final gynecologic cytology test reports from May 2024 failed to include the name and address of the laboratory where the test was performed. Findings include: 1. The Survey Team reviewed 155 final gynecologic cytology test reports from May 2024. a. One hundred fifty-five of 155 final gynecologic cytology test reports failed to indicate the name and address where the test was performed. Reports include: -HPMG24-00901 -HPMG24-00910 -HPMG24-00911 -HPMG24-00912 -HPMG24-00928 -HPMG24-00929 -HPMG24-00931 -HPMG24-00933 -HPMG24-00935 -HPMG24-00936 -HPMG24-00937 -HPMG24-00938 -HPMG24-00941 -HPMG24-00942 -HPMG24-00946 -HPMG24-00951 -HPMG24-00953 -HPMG24-00954 -HPMG24-00955 -HPMG24-00956 -HPMG24-00959 -HPMG24-00962 -HPMG24-00967 -HPMG24-00971 -HPMG24-00972 -HPMG24-00974 -HPMG24-00976 -HPMG24-00977 -HPMG24-00980 -HPMG24-00984 -HPMG24-00986 -HPMG24-00987 -HPMG24-00988 -HPMG24-00989 -HPMG24-00991 -HPMG24-00992 -HPMG24-00993 -HPMG24-00994 -HPMG24-00995 -HPMG24-00997 -HPMG24-00998 -HPMG24-00999 -HPMG24-01001 -HPMG24-01002 -HPMG24-01004 -HPMG24-01005 -HPMG24-

01006 -HPMG24-01007 -HPMG24-01008 -HPMG24-01009 -HPMG24-01010 -HPMG24-01011 -HPMG24-01014 -HPMG24-01017 -HPMG24-01018 -HPMG24-01019 -HPMG24-01020 -HPMG24-01021 -HPMG24-01022 -HPMG24-01024 -HPMG24-01025 -HPMG24-01026 -HPMG24-01027 -HPMG24-01028 -HPMG24-01031 -HPMG24-01034 -HPMG24-01037 -HPMG24-01039 -HPMG24-01042 -HPMG24-01043 -HPMG24-01045 -HPMG24-01046 -HPMG24-01047 -HPMG24-01049 -HPMG24-01052 -HPMG24-01055 -HPMG24-01056 -HPMG24-01057 -HPMG24-01058 -HPMG24-01059 -HPMG24-01064 -HPMG24-01066 -HPMG24-01070 -HPMG24-01072 -HPMG24-01073 -HPMG24-01076 -HPMG24-01077 -HPMG24-01080 -HPMG24-01081 -HPMG24-01116 -HPMG24-01118 -HPMG24-01120 -HPMG24-01121 -HPMG24-01122 -HPMG24-01123 -HPMG24-01124 -HPMG24-01125 -HPMG24-01127 -HPMG24-01129 -HPMG24-01130 -HPMG24-01131 -HPMG24-01133 -HPMG24-01135 -HPMG24-01136 -HPMG24-01137 -HPMG24-01138 -HPMG24-01140 -HPMG24-01141 -HPMG24-01142 -HPMG24-01174 -HPMG24-01176 -HPMG24-01178 -HPMG24-01179 -HPMG24-01180 -HPMG24-01182 -HPMG24-01184 -HPMG24-01192 -HPMG24-01193 -HPMG24-01194 -HPMG24-01197 -HPMG24-01200 -HPMG24-01201 -HPMG24-01202 -HPMG24-01203 -HPMG24-01206 -HPMG24-01208 -HPMG24-01209 -HPMG24-01210 -HPMG24-01211 -HPMG24-01240 -HPMG24-01241 -HPMG24-01242 -HPMG24-01245 -HPMG24-01246 -HPMG24-01248 -HPMG24-01249 -HPMG24-01251 -HPMG24-01252 -HPMG24-01253 -HPMG24-01257 -HPMG24-01258 -HPMG24-01261 -HPMG24-01264 -HPMG24-01265 -HPMG24-01270 -HPMG24-01271 -HPMG24-01273 -HPMG24-01275 -HPMG24-01277 -HPMG24-01307 -HPMG24-01308 -HPMG24-01309 -HPMG24-01310 -HPMG24-01311 -HPMG24-01314 2. During an interview on October 21, 2024 at 3:00 PM Anatomic Pathology Manager confirmed these findings stating that "the laboratory is working with the IT department to correct it".

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 review of laboratory policies and procedures, laboratory records and interviews the laboratory failed to have a Laboratory Director who provides overall management and direction in accordance with 493.1445 of this subpart. The Laboratory Director failed to be responsible for the overall operation and administration of the laboratory, for assuring compliance with applicable regulations (Refer to D6079); failed to ensure testing of samples for the annual gynecologic cytology PT program was performed in accordance with 493.801, which requires the laboratory to administer the gynecologic cytology PT events as required by the PT program's instructions (Refer to D6089).

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 the Laboratory Director failed to be responsible for the overall operation and administration of the laboratory, for assuring compliance with applicable regulations. Findings include: 1. The Laboratory Director failed to provide direction and oversight to ensure policies and procedures were established and followed for a program to detect errors in the performance of cytologic examinations. The Laboratory Director failed to ensure the case reviews of Cytotechnologists were evaluated against the laboratory's overall statistical values. Refer to D5631 2. The Laboratory Director failed to provide direction and oversight to ensure the final cytology test reports included the name and address of the laboratory where testing was performed. Refer to D5805

D6089

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:
Based on review of annual gynecologic cytology PT participation records and interviews the Laboratory Director failed to ensure testing of samples for the annual gynecologic cytology PT program was performed in accordance with 493.801, which requires the laboratory to not refer gynecologic cytology PT slidesets to another laboratory. The laboratory (Facility B) referred one gynecologic cytology PT slideset to Facility A in 2022. The laboratory (Facility B) referred two gynecologic cytology PT slidesets to Facility A in 2023. Findings include: 1. The laboratory delivered one gynecologic cytology PT slideset consisting of ten slides to Facility A in 2022 for analysis by Technical Supervisor A, Technical Supervisor B and Technical Supervisor C. Refer to D2013 2. The laboratory delivered two gynecologic cytology PT slidesets consisting of 10 slides each to Facility A in 2023 for analysis by Technical Supervisor A, Technical Supervisor B and Technical Supervisor C. Refer to D2013

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 workload records and interview the Technical Supervisor failed to reassess a maximum workload limit at least every six months for two of two Cytotechnologists in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Findings include: 1. The Technical Supervisor failed to provide documentation the Technical Supervisor reassessed a maximum workload limit at least every six months for two of two Cytotechnologists in 2022, 2023 and January 1, 2024 to the date of the survey in 2024. Refer to D5637 Cytotechnologists include: - Cytotechnologist A -Cytotechnologist B

D9999

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