

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0959387	(X3) Date Survey Completed 11/03/2025
Name of Provider or Supplier Propath Services Llc	Street Address, City, State 1600 Hospital Parkway, Bedford, 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
D0000	An onsite recertification survey was conducted on 11/03/2025. The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5631	<p>CYTOLOGY CFR(s): 493.1274(c)(6)</p> <p>(c)(6) An evaluation of the case reviews of each individual examining slides against the laboratorys overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, corrective actions taken. (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following:</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory annual statistical records, and confirmed in interview, the laboratory failed to perform individual versus laboratory statistics for four of five testing personnel performing non-gynecology primary and secondary screenings for 2023 and 2024. Findings included: 1. Review of laboratory policy titled "200919.522 SOP Off Site Non-Gyn Annual Statistic Report" stated: "PURPOSE The purpose of this procedure is to provide step-by-step instructions on printing the Non-Gyn list reported in each of the external facilities. The data is then collected and tracked in an annual statistic report ... PROCEDURE ... 4. Using the data collected, enter the results into the Form- Off-site Non-Gyn Annual Statistics report. NOTE: This report is maintained to monitor the volume and types of non-gyns specimens received from these facilities and is for internal QA purposes only. Records are maintained within the Cytology Department for up to 2 years. NOTE: Pathologist will be monitored and compared by their interpretation percentages for QA purposes. This will be tracked on an excel spreadsheet. Records are kept for 2 years." 2. Review of the laboratory's annual statistical records for 2023 and 2024 revealed no documentation of individual versus laboratory statistics for four of five testing</p>

personnel performing non-gynecology primary and secondary screenings as follows: TP-2 non-gyn secondary screener no records for 2023 and 2024 TP-3 non-gyn secondary screener no records for 2023 and 2024 TP-5 non-gyn primary screener no records for 2023 and 2024 TP-6 non-gyn primary screener no records for 2023 and 2024 On 11/03/2025 at 10:47 a.m. the laboratory was asked to provide documentation of the individual versus laboratory statistics for 2023 and 2024 and none was provided. 3. During an interview on 11/03/2025 at 10:47 a.m., the laboratory representatives, after a review of the records, confirmed the laboratory failed to perform individual versus laboratory statistics for four of five testing personnel performing non-gynecology primary and secondary screenings for 2023 and 2024. Word Key: Gyn- gynecology

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, cytology daily logs, annual test counts, and staff interview, the laboratory failed to follow written policies to ensure that a maximum workload limit was established for 2 of 2 cytotechnologists (CT-2, CT-3) performing cytology slide interpretations for gynecology and non-gynecology primary screenings in 2024 until date of the inspection in 2025. Findings included: 1. Review of the laboratory policy titled "200919.512 SOP Cytotechnologist Workload Limit Assessment" stated: "Workload Assessment Workload Limit Assessments are performed semi-annually for all Cytotechnologists. For new hires who have no prior experience with the Genius Digital Review system, NY workload assessment standards shall be followed and is performed every 3 months for the first year of employment. Thereafter, workload assessments are performed semi-annually as set by the Cytology Manager. The Cytology Manager performs the analysis and documents each Cytotechnologist's statistics in the workload assessment form (See Attachment 2). The following are considered by the Technical Supervisor in setting workload limits: Individual Cytotechnologist statistics relative to overall laboratory statistics. Other Notices of Interpretive Major Discrepancy received by a Cytotechnologist within the review period. Any other information deemed relevant to screening performance by the Technical Supervisor may be used in consideration of setting workload limits." 2. Review of cytology daily logs revealed two cytotechnologists (CT-2, CT-3) who performed gynecology and non-gynecology primary screenings. Further review of the logs revealed no workload limits were established for the above cytotechnologists in 2024 and 2025. 3. Review of the annual test counts found the laboratory reported performing 193 cytology slide interpretations for gynecology and non-gynecology primary screenings. 4. During an interview on 11/03/2025 at 10:33 a. m., the laboratory representatives, after a review of the records, confirmed the laboratory failed to follow written policies to ensure that a maximum workload limit was established for 2 of 2 cytotechnologists (CT-2, CT-3) performing cytology slide interpretations for gynecology and non-gynecology primary screenings in 2024 until the date of the inspection in 2025.

D5635

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

(d)(1)(i) The workload limit is based on the individual's performance using evaluations of the following: (d)(1)(i)(A) Review of 10 percent of the cases interpreted as negative for the conditions defined in paragraph (e)(1) of this section. (d)(1)(i)(B) Comparison of the individual's interpretation with the technical supervisor's confirmation of patient smears specified in paragraphs (e)(1) and (e)(3) of this section.

This STANDARD is not met as evidenced by:

Based on review of laboratory policies, cytology daily logs, annual test counts, and staff interview, the laboratory failed to ensure the workload limit was based on individual cytotechnologist's performance using evaluations of review of 10 percent of the cases interpreted as negative and the comparison of the individual cytotechnologist's interpretation with the technical supervisor's confirmation of patient smears when assessing the workload limit for two of two cytotechnologists performing cytology slide interpretations for gynecology and non-gynecology primary screenings in 2024 and to the date of the survey in 2025. Findings included: 1. Review of the laboratory policy titled "200919.512 SOP Cytotechnologist Workload Limit Assessment" stated: "Workload Assessment Workload Limit Assessments are performed semi-annually for all Cytotechnologists. For new hires who have no prior experience with the Genius Digital Review system, NY workload assessment standards shall be followed and is performed every 3 months for the first year of employment. Thereafter, workload assessments are performed semi-annually as set by the Cytology Manager. The Cytology Manager performs the analysis and documents each Cytotechnologist's statistics in the workload assessment form (See Attachment 2). The following are considered by the Technical Supervisor in setting workload limits: Individual Cytotechnologist statistics relative to overall laboratory statistics. Other Notices of Interpretive Major Discrepancy received by a Cytotechnologist within the review period. Any other information deemed relevant to screening performance by the Technical Supervisor may be used in consideration of setting workload limits." 2. Review of cytology daily logs revealed two cytotechnologists (CT-2, CT-3) who performed gynecology and non-gynecology primary screenings. Further review of the logs revealed no workload limits were established for the above cytotechnologists in 2024 and 2025. 3. Review of the annual test counts found the laboratory reported performing 193 cytology slide interpretations for gynecology and non-gynecology primary screenings. 4. During an interview on 11/03/2025 at 10:33 a. m., the laboratory representatives, after a review of the records, confirmed the laboratory failed to follow written policies to ensure the workload limit was based on individual cytotechnologist's performance using evaluations of review of 10 percent of the cases interpreted as negative and the comparison of the individual cytotechnologist's interpretation with the technical supervisor's confirmation of patient smears when assessing the workload limit for two of two cytotechnologists performing cytology slide interpretations for gynecology and non-gynecology primary screenings in 2024 and to the date of the survey in 2025.

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, cytology daily logs, annual test counts, and staff interview, the laboratory failed to reassess the workload limits at least once every six months 2 of 2 cytotechnologists (CT-2, CT-3) performing cytology slide interpretations for gynecology and non-gynecology primary screenings in 2024 until date of the inspection in 2025. Findings included: 1. Review of the laboratory policy titled "200919.512 SOP Cytotechnologist Workload Limit Assessment" stated: "Workload Assessment Workload Limit Assessments are performed semi-annually for all Cytotechnologists. For new hires who have no prior experience with the Genius Digital Review system, NY workload assessment standards shall be followed and is performed every 3 months for the first year of employment. Thereafter, workload assessments are performed semi-annually as set by the Cytology Manager. The Cytology Manager performs the analysis and documents each Cytotechnologist's statistics in the workload assessment form (See Attachment 2). The following are considered by the Technical Supervisor in setting workload limits: Individual Cytotechnologist statistics relative to overall laboratory statistics. Other Notices of Interpretive Major Discrepancy received by a Cytotechnologist within the review period. Any other information deemed relevant to screening performance by the Technical Supervisor may be used in consideration of setting workload limits." 2. Review of cytology daily logs revealed two cytotechnologists (CT-2, CT-3) who performed gynecology and non-gynecology primary screenings. Further review of the logs revealed no workload limits were established for the above cytotechnologists in 2024 and 2025. 3. Review of the annual test counts found the laboratory reported performing 193 cytology slide interpretations for gynecology and non-gynecology primary screenings. 4. During an interview on 11/03/2025 at 10:33 a.m., the laboratory representatives, after a review of the records, confirmed the laboratory failed to reassess the workload limits at least once every six months 2 of 2 cytotechnologists (CT-2, CT-3) performing cytology slide interpretations for gynecology and non-gynecology primary screenings in 2024 until date of the inspection in 2025.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on review of Center for Medicare & Medicaid Services (CMS) 209 form, personnel records, and confirmed in interview, the laboratory director failed to specify in writing the responsibilities and duties of each person involved in all phases of the testing process that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results for two of three cytotechnologists (CT-2, CT-3). Findings included: 1. Review of the CMS 209 form identified three testing personnel identified as cytotechnologists. 2. Review of personnel records for CT-2 and CT-3 revealed no written documentation of the duties and responsibilities by the laboratory director for CT-2 and CT-3. 3. During an interview on 11/03/2025 at 9:40 a.m., the

laboratory representatives, after a review of the records, confirmed the laboratory director failed to specify in writing the responsibilities and duties of each person involved in all phases of the testing process that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results for two of three cytotechnologists (CT-2, CT-3).

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:
Based on review of Center for Medicare & Medicaid Services (CMS) 209 form, laboratory policy, personnel records, and confirmed in interview, the technical supervisor failed to evaluate and document the annual performance of individuals responsible for high complexity testing for two of three cytotechnologists (CT-2, CT-3) in 2024 and 2025. Findings included: 1. Review of the CMS 209 form identified three testing personnel identified as cytotechnologists. 2. Review of laboratory policy titled "5032 Orientation, Training, Competency, and Continuing Education" stated: "7.0 Competency Assessment 7.1 On an annual basis, all employees will be assigned job specific competencies in MediaLab which will assess competence on all test systems performed." 3. Review of personnel records for CT-2 and CT-3 revealed the following: CT-2 2024 and 2025 annual competency assessments were performed by a person who was NOT delegated on the CMS 209 form as the technical supervisor. CT-3 2024 annual competency assessment was performed by CT-2 who was NOT delegated on the CMS 209 form as the technical supervisor. 4. During an interview on 11/03/2025 at 10:33 a.m., the laboratory representatives, after a review of the records, confirmed the technical supervisor failed to evaluate and document the annual performance of individuals responsible for high complexity testing for two of three cytotechnologists (CT-2, CT-3) in 2024 and 2025.

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 the Based on review of laboratory policies, cytology daily logs, annual test counts, and staff interview, the technical supervisor failed to ensure a maximum workload limit was established and reassessed at least once every six months for two of two cytotechnologists performing cytology slide interpretations for gynecology and non-gynecology primary screenings in 2024 and to the date of the survey in 2025. Refer to D5633, D5635, and D5637.