

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0502642	<b>(X3) Date Survey Completed</b>  12/12/2022
<b>Name of Provider or Supplier</b>  Histopath Inc	<b>Street Address, City, State</b>  4455 S Padre Island Drive, Suite 39, Corpus Christi, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) results, and confirmed in interview of laboratory personnel, the laboratory failed to provide documentation of its review of results for 5 of 5 events reviewed from 2021 (event B) and 2022 (events A and B). The findings included: 1. A review of the laboratory's CAP proficiency testing results from 2021 (event B) and 2022 (events A and B) found the laboratory failed to have documentation of its review of results for each of the following 5 events: HER2-B (2021) PM2-B (2021) HER2-A (2022) HER2-B (2022) PM2-A (2022) 2. The laboratory was asked to provide documentation of the missing review of results. No documentation was provided. 3. An interview with testing personnel number #6 (as listed on Form CMS 209) and the Practice Manager on December 12, 2022 at 11:30 hours in the conference room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services HER2 - Human Epidermal Growth Factor Receptor 2 PM2 Program - CAP proficiency testing program that fulfills Estrogen and Progesterone Receptors</p>
<b>D5215</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score</p>

for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on review of the laboratory's College of American Pathologists (CAP) proficiency testing records, and confirmed in interview of laboratory personnel, the laboratory failed to have documentation of evaluating ungraded proficiency testing results for 4 of 4 events reviewed from 2021 (event B) and 2022 (events A and B). The findings were: 1. A review of the laboratory's College of American Pathologists (CAP) proficiency testing records from 2021 (event B) and 2022 (events A and B) found the following exception legend codes: [26] = Educational challenge [27] = Lack of consensus For these scores, the laboratory must perform self-evaluation. 2. Further review of the laboratory's College of American Pathologists (CAP) proficiency testing records from 2021 (event B) and 2022 (events A and B) found the laboratory failed to perform self-evaluation for results ungraded by the proficiency testing agency for the following 4 of 4 events reviewed: Event ID: HER2-B (2021) Test Specimen Score Core 02 HER2-03 27 Core 09 HER2-04 27 Wild Card Her2-04 26 Challenge Event ID: HER2-A (2022) Test Specimen Score Core 08 HER2-01 27 Core 07 HER2-02 27 Event ID: PM2-A (2022) Test Specimen Score ER Core 1 PM2-01 26 Intensity ER Core 2 PM2-01 26 Intensity ER Core 3 PM2-01 26 Intensity ER Core 5 PM2-01 26 Intensity ER Core 7 PM2-01 26 Intensity ER Core 9 PM2-01 26 Intensity ER Core 2 PM2-02 26 Intensity ER Core 3 PM2-02 26 Intensity ER Core 5 PM2-02 26 Intensity ER Core 6 PM2-02 26 Intensity ER Core 7 PM2-02 26 Intensity ER-WC Core 14 PM2-02 26 PgR Core 3 PM2-03 26 Intensity PgR Core 4 PM2-03 26 Intensity PgR Core 6 PM2-03 26 Intensity PgR Core 7 PM2-03 26 Intensity PgR Core 8 PM2-03 26 Intensity PgR Core 1 PM2-04 26 Intensity PgR Core 4 PM2-04 26 Intensity PgR Core 6 PM2-04 26 Intensity PgR Core 8 PM2-04 26 Intensity PgR Core 9 PM2-04 26 Intensity PgR Core 10 PM2-04 26 Intensity Event ID: HER2-B (2022) Test Specimen Score Core 01 HER2-04 27 Core 06 HER2-04 27 Core 09 HER2-04 27 3. The laboratory was asked to provide documentation of performing a self-evaluation of its proficiency testing results to assess their accuracy. No documentation was provided. 4. An interview with the Practice Manager and Testing Personnel #6 (as listed on Form CMS 209) on December 12, 2022 at 11:30 hours in the conference room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services HER2 - Human Epidermal Growth Factor Receptor 2 PgR - Progesterone Receptor ER - Estrogen Receptor

**D6143**

**GENERAL SUPERVISOR QUALIFICATIONS**

CFR(s): 493.1461

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i)

Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493.1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(1)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:

Based on review of the laboratory's personnel records, review of patient records, and confirmed in interview, the laboratory failed to review within 24 hours of all physical examinations/descriptions of tissue including color, weight, measurement and other characteristics of the tissue; or other mechanical procedures (grossing) for 9 of 9 samples randomly reviewed from December 2021 and January 2022. The findings included: 1. A review of the laboratory's personnel records for testing personnel #4, testing personnel #5, and testing personnel #6 (as listed on Form CMS 209) found no documentation of records to qualify them as a laboratory director or technical supervisor for high complexity testing in the specialty of histopathology. Therefore, grossing must be reviewed by a technical supervisor within 24 hours. 2. A random review of 9 of 9 patient reports whose grossing was performed from December 2021 and January 2022 did not document review of the grossing by the technical supervisor (TS) within 24 hours. Pathology Number Date of Final Diagnosis CY-21-01596 01-03-2022 CY-21-01597 01-03-2022 HP-21-05135 01-03-2022 HP-21-05134 01-03-

2022 ST-22-00001 01-04-2022 ST-22-00002 01-04-2022 ST-21-04415 01-03-2022  
ST-22-00003 01-04-2022 ER-22-00005 01-12-2022 3. An interview with the Practice  
Manager on December 12, 2022 at 12:15 hours in the conference room confirmed the  
findings. Key: CMS - Centers for Medicare and Medicaid Services