

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2171511	(X3) Date Survey Completed 09/29/2021
Name of Provider or Supplier Pathzone Llc	Street Address, City, State 11215 Oudney Ct, Richmond, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, laboratory quality control stain</p>

logs from 2020 to 2021, and confirmed in interview, the laboratory failed to implement a written procedure that defined the control procedures to assess for stain quality for four of four Immunohistochemical stains (MLH1, MSH2, MSH6, PMS2). Findings included: 1. Review of the laboratory's procedure manual did not include a procedure for assessing the stain quality for four of four immunohistochemical stains (MLH1, MSH2, MSH6, PMS2). The following components were not included for the stains: a) Control procedures b) Corrective actions to take for unacceptable stain quality and results 2. Review of the laboratory quality control stain from 2020 to 2021 revealed no documentation the laboratory assessed for the four immunohistochemical stains. Refer to D5601 3. Random review of the laboratory patient test records from 2020 to 2021 revealed the laboratory performed the following patient specimen for the above IHC stains. Accession #UP21-503559 4. An interview with the laboratory director on 9/28/21 at 1120 hours in her office confirmed the above findings. II. Based on review of the laboratory's procedure manual, laboratory quality control stain logs from 2020 to 2021, and confirmed in interview, the laboratory failed to implement a written procedure that defined the control procedures to assess for stain quality for 3 of 3 differential stains (H&E (hematoxylin & eosin), PAS, and hema diff). Findings included: 1. Review of the laboratory's procedure manual did not include a procedure for assessing the stain quality for 3 of 3 special stains (H&E, PAS, and hema diff). The following components were not included for the stains: a) Control procedures b) Corrective actions to take for unacceptable stain quality and results 2. Review of the laboratory quality control stain from 2020 to 2021 revealed the laboratory assessed the following 3 quality control stain quality: H&E, PAS, and hema diff for seven of seven days reviewed. 7/15/20 7/28/20 9/29/20 4/8/21 7/26/21 7/30/21 9/28/21 3. Random review of the laboratory patient test records from 2020 to 2021 revealed the laboratory performed the following seven patient specimens for the above dates. 7/15/20: UP20-503998 7/28/20: UP20-504390 9/29/20: UP20-506297 4/08/21: UP21-502559 7/26/21: UP21-506218 7/30/21: UP21-506454 9/28/21: UP21-508419 4. An interview with the laboratory director on 9/28/21 at 1120 hours in her office confirmed the above findings. key: MLH1, MSH2, MSH6, PMS2 - IHC stain to determine Hereditary nonpolyposis colon cancer (HNPCC), also known as Lynch syndrome, is an autosomal dominant inherited cancer syndrome that predisposes individuals to the development of colorectal, endometrial, gastric, upper urinary tract, and other cancers. Individuals with HNPCC/Lynch syndrome have a germline mutation in 1 of several genes involved in DNA mismatch repair. The majority of mutations associated with HNPCC/Lynch syndrome occur in MSH2 and MLH1; however, mutations in MSH6 and PMS2 have also been identified.

D5601

HISTOPATHOLOGY
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of laboratory patient result from 2020 to 2021, laboratory quality control records, and confirmed in interview, the laboratory failed to document the stain quality of known positive and negative reactivity with each patient slide or group

of patient slides when assessing the professional component of four of four immunohistochemical stains (IHC): MLH1, MSH2, MSH6, PMS2. Findings were: 1. Random review of patient test records from 2020 to 2021 revealed one of ten test reports with professional interpretation for the following stains: Accession #UP21-503559 IHC stain MLH1 MSH2 MSH6 PMS2 2. Review of the quality control records for the above date revealed no documentation of the stain quality of known positive and negative reactivity of the above stains. 3. An interview of the laboratory director on 09/29/21 1135 hours in her office confirmed the above findings. key: MLH1, MSH2, MSH6, PMS2 - IHC stain to determine Hereditary nonpolyposis colon cancer (HNPCC), also known as Lynch syndrome, is an autosomal dominant inherited cancer syndrome that predisposes individuals to the development of colorectal, endometrial, gastric, upper urinary tract, and other cancers. Individuals with HNPCC /Lynch syndrome have a germline mutation in 1 of several genes involved in DNA mismatch repair. The majority of mutations associated with HNPCC/Lynch syndrome occur in MSH2 and MLH1; however, mutations in MSH6 and PMS2 have also been identified.

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(l)(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 patient test reports from July and September 2021 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 for one of five reports reviewed. Finding were: 1. A random review of the patient reports from July 2021 and September 2021 revealed one of five test reports which did not document review of the grossing by the technical supervisor (TS) within 24 hours. UP21-506218 Collected 7/21/21; received 7/22/21; reviewed 7/26/21; elapsed time 4 days 2. An interview with the laboratory director on 9/28/21 at 1120 hours in her office confirmed that there is no review of the grossing. She stated that she typically reviews the slide the following day but that on the weekend (sample above) they are not reviewed until the following Monday.