Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2122137	05/19/2021
Name of Provider or Supplier	**Street Address, City, State**	
Precise Diagnostics, Llc	2695 Villa Creek Dr Ste B255, Farmers Branch, 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 entrance conference was held with the laboratory representative. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives 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. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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: I. Based on review of laboratory policies, a random review of quality control records (2020 and 2021), and confirmed in interview, the laboratory failed to follow its own written policy for slide staining quality control acceptability. Findings included: 1. The laboratory policy titled, "Technical Quality Control" (signed by the laboratory director 03/03/2020), stated the following: "Objective: To assure the consistent quality of microscopic slides, the following criteria should be met and graded daily on the

"Histology Quality Control' log for stain(s) performed that day by the Pathologist... Policy: After staining and cover slipping, slides are checked for the quality of stain and general appearance of slides by looking at both the stain control and patient slides. A slide/block check is performed to ensure that both the patient's name and accession number match before slide distribution. Slides are placed in accordance to transcribed dictation into a slide folder in ascending order, with each slide folder paired with the stack of requisitions sorted in numerical order to correspond with that of the slides, this is then given to the pathologist(s). The slide 'Histology Quality Control' Log is also submitted to the Pathologist to document review of the slide quality daily." 2. Review of the laboratory policy titled, "H&E Stain" (signed by the laboratory director 03/03/2020), stated, "...Quality Control: ...The Pathologist will review and document stain quality on the 'Histology Quality Control' log." 3. Review of the laboratory policy titled, "GMS-Methenamine Silver-Groscott's Modified Fungal Stain" (signed by the laboratory director 03/03/2020), stated, "...Quality Control: ... The Pathologist will review and document stain quality on the 'Histology Quality Control' log." 4. Review of the laboratory policy titled, "H&E Stain" (signed by the laboratory director 03/03/2020), stated, "...Quality Control: ...The Pathologist will review and document stain quality on the 'Histology Quality Control' log." 5. Review of the laboratory quality control form titled "Histology Quality Control" revealed the form included Case numbers submitted for review, date, area for pathologist's signature/date and the following questions to be answered by the reviewing pathologist: "1. Did the H&E stain appropriately? Y N If no, please explain: 2. Did the PAS control demonstrate adequate fungus? Y N If no, please explain: 3. Did the GMS control demonstrate adequate fungus? Y N If no, please explain: 4. Were there any issues with technical quality? Y N If yes, please list the issues (floaters, poor sections, etc)" 6. Further review of the laboratory quality control records revealed the following days when documentation of pathologist review of stain quality was incomplete: a. Case #s PD20-270-293; Date: 02/04/2020 No response to questions 1, 2, 3, and 4 by reviewing pathologist. No documentation of pathologist signature and date. b. Case #s PD20-882-8913; Date: 03/18/2020; GMS stain only No response to question 3 by reviewing pathologist. No documentation of pathologist signature and date. c. Case #s PD20-1015, PD20-1017-1025; Date: 03/24/2020 No response to questions 1, 2, 3, and 4 by reviewing pathologist. No documentation of pathologist signature and date. d. Case #s PD20-1058-1066; Date: 03/31/2020 No response to questions 1, 2, 3, and 4 by reviewing pathologist. e. Case #s PD20-1047-1054; Date: 03/31/2020; GMS stain only No response to question 3 by reviewing pathologist. f. Case #s PD20-2959-2966; Date: 11/11/2020 No documentation of pathologist signature and date. g. Case #s PD21-812, 819-826; Date: 03/30/2021 No response to questions 1, 2, 3, and 4 by reviewing pathologist. No documentation of pathologist signature and date. h. Case #s PD21-841-846; Date: 03/31/2021 No response to questions 1, 2, 3, and 4 by reviewing pathologist. The laboratory failed to follow its own written policy to ensure documentation of slide staining quality control acceptability by the reviewing pathologist. 7. In an interview on 05/19/2021 at 09: 15am in the breakroom, Testing Person #2, after review of the quality control records, confirmed the above findings. Word Key: H&E=Hematoxylin and Eosin PAS=Periodic acid Schiff GMS=Grocott's methenamine silver Y=Yes N=No II. Based on review of laboratory policy, random review of patient test requisitions, and confirmed in interview, the laboratory failed to follow its own written policy for test requisition information for 8 of 34 patient requisitions in 2020 (01/2021 through 05/19 /2021). Findings included: 1. The laboratory policy titled, "Specimen Collection, Handling, and accessioning of Tissues (non-Fluids)" (signed by the laboratory director 03/03/2020), stated the following: "Specimen Collection: A. Pre-Laboratory handling of specimens: 1. All specimens must be accompanied by a requisition, which should

manually include the following information: a. Patient name b. Birthdate c. Gender d. Medical practitioner name who obtained the specimen e. Name and address of medical practitioner's office or origin f. Specimen source (body site of origin) g. Pertinent medical history and/or clinical data and/or differential diagnosis (one or more) h. Patient insurance information ..." 2. A random review of patient requisitions from 01/2021 through 05/19/2021 revealed the following 8 of 34 requisitions that failed to include the name and address of the medical practitioner's office or origin: a. 01/15/2021: Patient PD21-0155 b. 03/05/2021; Patient PD21-0599 c. 03/09/2021; Patient PD21-0655 d. 04/01/2021; Patient PD21-1012 e. 04/06/2021; Patient PD21-1014 f. 04/07/2021; Patient PD21-1013 g. 04/07/2021; Patient PD21-1015 h. 05/18 /2021; Patient PD21-1503 The laboratory failed to ensure the patient requisition included the name and address of the medical practitioner's office or origin per laboratory policy. 3. In an interview of 05/19/2021 at 12:20pm in the breakroom, Testing Person #2, after to review of the patient requisition forms, confirmed the above the findings. 40420 III. Based on review of laboratory policies, CMS 209 form, patient test requisitions, specimen grossing review forms, and confirmed in interview, the laboratory failed to follow its own written policy for grossing of histology specimens for 26 of 26 patient specimens in 2020 (06/2020, 12/2020) and 48 and 48 patient specimens in 2021 (01/2021-04/2021). Findings: 1. Review of the laboratory's policy "Policy# SP-106" revealed: "Accessioning ... Documenting Gross Dictation: All specimens are grossed by histotechnicians under the direct supervision of the Pathologist/Medical Director. Each specimen is grossed one at a time. All required information on the requisition is checked against specimen container for verification. Specimens are grossed documenting the measurements and noting any discolorations or lesions." 2. Review of the CMS 209 form listed the laboratory director as the clinical consultant, general supervisor (GS), technical supervisor (TS) and testing person (TP). The form included three additional general supervisors/testing persons (GS-2/TP-5, GS-3/TP-6, GS-4/TP7) who perform reading and interpretation of the slides and also included six additional testing persons (TP-2, TP-3, TP-4, TP-8, TP-9, TP-10), who performed the gross examinations of specimens received from outside clients. The laboratory director/general supervisor/technical supervisor was not onsite. GS-2/TP-5, GS-3/TP-6, GS-4/TP-7 were also not onsite. TP-2, TP-3, TP-4, TP-8, TP-9, TP-10 did not qualify as general supervisors or technical supervisors, requiring review within 24 hours. Gross examination included all documented physical examination/descriptions including measurement of the specimen. 3. During an interview on 05/19/2021 at 10:40 am, TP-2 stated that grossing was reviewed by the pathologists (general supervisors) when they would come into the laboratory to pick up slides. She stated that the pathologist would review the grossing by reviewing the specimen blocks. TP-2 stated that the only direct supervision of grossing was during training and no other direct supervision of grossing was performed on a day to day basis. The laboratory failed to perform direct supervision of grossing, as required by their own written policy. 4. Review of patient test requisitions revealed gross examinations were documented on the requisitions and included initials of TP-2 or TP-3. Review of the Specimen Grossing Log revealed gross examinations were reviewed and signed by the LD/GS-1, GS-2/TP-5 or GS-4/TP-7. The following patient specimens were grossed without direct supervision in 2020 and 2021, as required by their own written policy: Grossing date: 06/24/2020; Grossing review date: 06/20 /2020 Specimen #: PD20-1854, PD20-1855, PD20-1856 Grossing date: 12/28/2020; Grossing review date: 12/30/2020 Specimen #: PD20-3344, PD20-3345, PD20-3346, PD20-3347, PD20-3348, PD20-3349, PD20-3350, PD20-3351, PD20-3352, PD20-3353, PD20-3354, PD20-3355, PD20-3356, PD20-3357, PD20-3358, PD20-3359, PD20-3360, PD20-3361, PD20-3363, PD20-3364, PD20-3365, PD20-3366, PD20-3367 Grossing date: 01/12/2021; Grossing review date: 01/14/2021 Specimen #:

	PD21-0063, PD21-0064, PD21-0065, PD21-0066, PD21-0067, PD21-0068, PD21-0069, PD21-0070, PD21-0071, PD21-0072, PD21-0073, PD21-0074, PD21-0075, PD21-0076, PD21-0077 Grossing date: 03/09/2021; Grossing was NOT reviewed by a general supervisor Specimen #: PD21-0575, PD21-0576, PD21-0577, PD21-0578, PD21-0579, PD21-0580, PD21-0581, PD21-0582, PD21-0583, PD21-0584, PD21-0585, PD21-0586, PD21-0587, PD21-0588, PD21-0589, PD21-0590, PD21-0591, PD21-0592, PD21-0593, PD21-0594, PD21-0595, PD21-0596, PD21-0597, PD21-0598 Grossing date: 03/11/2021; Grossing review date: 03/13/2021 Specimen #: PD21-0626, PD21-0627, PD21-0628, PD21-0629, PD21-0630, PD21-0631 Grossing date: 04/15/2021; Grossing review date: 04/19/2021 Specimen #: PD21-0638, PD21-0639, PD21-0640 5. During the exit interview on 05/19/2021 at 12:20 pm, TP-2 confirmed the laboratory failed to follow their own written policy for direct observation of grossing by the pathologist.
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 laboratory policies, Center for Medicare & Medicaid Services (CMS) 209 form, patient test requisitions, specimen grossing review forms, and confirmed in interview, the general supervisor failed to ensure gross examinations for patient specimens performed by testing persons were reviewed within 24 hours for 26 of 26 patient specimens in 2020 (06/2020, 12/2020) and 48 and 48 patient specimens in 2021 (01/2021-04/2021). Findings: 1. Review of the laboratory's policy titled "Policy# SP-107" revealed: "Specimen Grossing Review: All specimen blocks and gross descriptions from the requisitions are reviewed and verified to match by the pathologist prior to microscopic examination within 24 hours. This is documented by the pathologist on the "Specimen Grossing Review Form"". 2. Review of the CMS 209 form listed the laboratory director as the clinical consultant, general supervisor (GS), technical supervisor (TS) and testing person (TP). The form included three additional general supervisors/testing persons (GS-2/TP-5, GS-3/TP-6, GS-4/TP7) who perform reading and interpretation of the slides and also included six additional testing persons (TP-2, TP-3, TP-4, TP-8, TP-9, TP-10), who performed the gross examinations of specimens received from outside clients. The laboratory director /general supervisor/technical supervisor was not onsite. GS-2/TP-5, GS-3/TP-6, GS-4 /TP-7 were also not onsite. TP-2, TP-3, TP-4, TP-8, TP-9, TP-10 did not qualify as general supervisors or technical supervisors, requiring review within 24 hours. Gross examination included all documented physical examination/descriptions including measurement of the specimen. 3. During an interview on 05/19/2021 at 10:40 am, TP-2 stated that grossing was reviewed by the pathologists (general supervisors) when they would come into the laboratory to pick up slides. She stated that the pathologist would review the grossing by reviewing the specimen blocks. 4. Review of patient test requisitions revealed gross examinations were documented on the requisitions and included initials of TP-2 or TP-3. Review of the Specimen Grossing Log revealed gross examinations were reviewed and signed by the LD/GS-1, GS-2/TP-5 or GS-4 /TP-7. There was no documentation of the TS/GS review of the specimen blocks within 24 hours of the gross examinations for TP-2 or TP-3. The following patient specimens were not reviewed within 24 hours in 2020 and 2021 as required: Specimen #: PD20-1854 Test requisition date received: 06/24/2020, test requisition included grossing examination, TP-3 initials and date (06/24/2020) Specimen Grossing Log signed by GS-2 on 06/26/2020, indicating review of grossing. Specimen #: PD20-1855 Test requisition date received: 06/24/2020, test requisition included grossing examination, TP-3 initials and date (06/24/2020) Specimen Grossing Log signed by GS-2 on 06/26/2020, indicating review of grossing. Specimen #: PD20-1856 Test requisition date received: 06/24/2020, test requisition included grossing

examination, TP-3 initials and date (06/24/2020) Specimen Grossing Log signed by GS-2 on 06/26/2020, indicating review of grossing. Specimen #: PD20-3344 Test requisition date received: 12/23/2020, test requisition included grossing examination, TP-2 initials and date (12/28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3345 Test requisition date received: 12/23/2020, test requisition included grossing examination, TP-2 initials and date (12/28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3346 Test requisition date received: 12/23/2020, test requisition included grossing examination, TP-2 initials and date (12 /28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3347 Test requisition date received: 12/23/2020, test requisition included grossing examination, TP-2 initials and date (12/28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3348 Test requisition date received: 12/23/2020, test requisition included grossing examination, TP-2 initials and date (12/28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3349 Test requisition date received: 12/23/2020, test requisition included grossing examination, TP-2 initials and date (12 /28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3350 Test requisition date received: 12/23/2020, test requisition included grossing examination, TP-2 initials and date (12/28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3351 Test requisition date received: 12/23/2020, test requisition included grossing examination, TP-2 initials and date (12/28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3352 Test requisition date received: 12/23/2020, test requisition included grossing examination, TP-2 initials and date (12 /28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3353 Test requisition date received: 12/23/2020, test requisition included grossing examination, TP-2 initials and date (12/28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3354 Test requisition date received: 12/23/2020, test requisition included grossing examination, TP-2 initials and date (12/28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3355 Test requisition date received: 12/23/2020, test requisition included grossing examination, TP-2 initials and date (12 /28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3356 Test requisition date received: 12/23/2020, test requisition included grossing examination, TP-2 initials and date (12/28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3357 Test requisition date received: 12/23/2020, test requisition included grossing examination, TP-2 initials and date (12/28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3358 Test requisition date received: 12/23/2020, test requisition included grossing examination, TP-2 initials and date (12 /28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3359 Test requisition date received: 12/23/2020, test requisition included grossing examination,

TP-2 initials and date (12/28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3360 Test requisition date received: 12/23/2020, test requisition included grossing examination, TP-2 initials and date (12/28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3361 Test requisition date received: 12/28/2020, test requisition included grossing examination, TP-2 initials and date (12 /28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3363 Test requisition date received: 12/28/2020, test requisition included grossing examination, TP-2 initials and date (12/28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3364 Test requisition date received: 12/28/2020, test requisition included grossing examination, TP-2 initials and date (12/28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3365 Test requisition date received: 12/28/2020, test requisition included grossing examination, TP-2 initials and date (12 /28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3366 Test requisition date received: 12/28/2020, test requisition included grossing examination, TP-2 initials and date (12/28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD20-3367 Test requisition date received: 12/28/2020, test requisition included grossing examination, TP-2 initials and date (12/28; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 12/30/2020, indicating review of grossing. Specimen #: PD21-0063 Test requisition date received: 01/11/2021, test requisition included grossing examination, TP-2 initials and date (01 /12; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 01/14/2021, indicating review of grossing. Specimen #: PD21-0064 Test requisition date received: 01/11/2021, test requisition included grossing examination, TP-2 initials and date (01/12; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 01/14/2021, indicating review of grossing. Specimen #: PD21-0065 Test requisition date received: 01/11/2021, test requisition included grossing examination, TP-2 initials and date (01/12; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 01/14/2021, indicating review of grossing. Specimen #: PD21-0066 Test requisition date received: 01/11/2021, test requisition included grossing examination, TP-2 initials and date (01 /12; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 01/14/2021, indicating review of grossing. Specimen #: PD21-0067 Test requisition date received: 01/11/2021, test requisition included grossing examination, TP-2 initials and date (01/12; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 01/14/2021, indicating review of grossing. Specimen #: PD21-0068 Test requisition date received: 01/11/2021, test requisition included grossing examination, TP-2 initials and date (01/12; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 01/14/2021, indicating review of grossing. Specimen #: PD21-0069 Test requisition date received: 01/11/2021, test requisition included grossing examination, TP-2 initials and date (01 /12; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 01/14/2021, indicating review of grossing. Specimen #: PD21-0070 Test requisition date received: 01/11/2021, test requisition included grossing examination, TP-2 initials and date (01/12; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 01/14/2021, indicating review of grossing. Specimen #: PD21-0071 Test requisition date received: 01/11/2021, test requisition

included grossing examination, TP-2 initials and date (01/12; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 01/14/2021, indicating review of grossing. Specimen #: PD21-0072 Test requisition date received: 01/11/2021, test requisition included grossing examination, TP-2 initials and date (01 /12; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 01/14/2021, indicating review of grossing. Specimen #: PD21-0073 Test requisition date received: 01/11/2021, test requisition included grossing examination, TP-2 initials and date (01/12; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 01/14/2021, indicating review of grossing. Specimen #: PD21-0074 Test requisition date received: 01/11/2021, test requisition included grossing examination, TP-2 initials and date (01/12; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 01/14/2021, indicating review of grossing. Specimen #: PD21-0075 Test requisition date received: 01/11/2021, test requisition included grossing examination, TP-2 initials and date (01 /12; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 01/14/2021, indicating review of grossing. Specimen #: PD21-0076 Test requisition date received: 01/11/2021, test requisition included grossing examination, TP-2 initials and date (01/12; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 01/14/2021, indicating review of grossing. Specimen #: PD21-0077 Test requisition date received: 01/11/2021, test requisition included grossing examination, TP-2 initials and date (01/12; there was no year included just month and day) Specimen Grossing Log signed by GS-2 on 01/14/2021, indicating review of grossing. Specimen #: PD21-0575 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03 /09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0576 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0577 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0578 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0579 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0580 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0581 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0582 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0583 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen.

Specimen #: PD21-0584 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0585 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0586 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0587 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0588 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0589 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0590 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0591 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0592 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0593 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0594 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0595 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0596 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0597 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0598 Test requisition date received: 03/08/2021, test requisition included grossing examination, TP-3 initials and date (03/09/21) Specimen Grossing Log was NOT signed by a general supervisor. The laboratory failed to review grossing for the patient specimen. Specimen #: PD21-0626 Test requisition date received: 03/11/2021, test requisition included grossing examination, TP-3 initials and date (03/11/21) Specimen Grossing

	Log signed by GS-4 on 03/13/2021 indicating review of grossing. Specimen #: PD21-0627 Test requisition date received: 03/11/2021, test requisition included grossing examination, TP-3 initials and date (03/11/21) Specimen Grossing Log signed by GS-4 on 03/13/2021 indicating review of grossing. Specimen #: PD21-0628 Test requisition date received: 03/11/2021, test requisition included grossing examination, TP-2 initials and date (03/11; there was no year included just month and day) Specimen Grossing Log signed by GS-4 on 03/13/2021 indicating review of grossing. Specimen #: PD21-0629 Test requisition date received: 03/11/2021, test requisition included grossing examination, TP-2 initials and date (03/11; there was no year included just month and day) Specimen Grossing Log signed by GS-4 on 03/13/2021 indicating review of grossing. Specimen #: PD21-0630 Test requisition date received: 03/11/2021, test requisition included grossing examination, TP-2 initials and date (03 /11; there was no year included just month and day) Specimen Grossing Log signed by GS-4 on 03/13/2021 indicating review of grossing. Specimen #: PD21-0631 Test requisition date received: 03/11/2021, test requisition included grossing examination, TP-2 initials and date (03/11; there was no year included just month and day) Specimen Grossing Log signed by GS-4 on 03/13/2021 indicating review of grossing. Specimen #: PD21-0638 Test requisition date received: 04/15/2021, test requisition included grossing examination, TP-2 initials and date (04/15; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 04/19/2021 indicating review of grossing. Specimen #: PD21-0639 Test requisition date received: 04/15/2021, test requisition included grossing examination, TP-2 initials and date (04 /15; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 04/19/2021 indicating review of grossing. Specimen #: PD21-0640 Test requisition date received: 04/15/2021, test requisition included grossing examination, TP-2 initials and date (04/15; there was no year included just month and day) Specimen Grossing Log signed by GS-1 on 04/19/2021 indicating review of grossing. The laboratory did not ensure specimen blocks were reviewed and documented within 24 hours by the TS/GS, as required. 5. During an interview on 05/19/2021 at 10:40 am, TP-2 confirmed the above findings.