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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 23D2295414 | (X3) Date Survey Completed 11/04/2024 |
| Name of Provider or Supplier Yu Pathology | Street Address, City, State 4720 Rivers Edge Drive, Troy, MI | |
| 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 |
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| D5028 | <p>HISTOPATHOLOGY CFR(s): 493.1219</p> <p>If the laboratory provides services in the subspecialty of Histopathology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1273, and 493.1281 through 493.1299.</p> <p>This CONDITION is not met as evidenced by: . Based on record review and interview, the laboratory failed to establish a written procedure for microscopic tissue examination (refer to D5401), failed to document stain quality for Hematoxylin and Eosin (H&E) Staining (Refer to D5473), failed to document quality control for Immunohistochemistry (IHC) Positive and Negative controls (Refer to D5601) and failed to retain slides for 5 (#2-6) of 6 patient test records reviewed (Refer to D5603).</p> |
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to establish a competency assessment policy for 11 (November 2023 - October 2024) of 11 months. Findings include: 1. A record review revealed that the laboratory did not have a policy for competency assessments. 2. An interview on 11/04/2024 at 3:10 pm with the Laboratory Director confirmed that a competency assessment policy had not been established.</p> |

D5305

TEST REQUEST

CFR(s): 493.1241(c)

The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Laboratory Director, the laboratory failed to list the laboratory name and address on 6 (#1-6) of 6 patient test reports reviewed. Findings include: 1. A review of 6 patient records revealed that the name and address of the laboratory were not included on the patient test reports for microscopic tissue examination: a. Patient 1: Tested on 10/31/2024 b. Patient 2: Tested on 9/26/2024 c. Patient 3: Tested on 7/3/2024 d. Patient 4: Tested on 5/30/2024 e. Patient 5: Tested on 2/27/2024 f. Patient 6: Tested on 11/16/2023 2. An interview with the Laboratory Director on 11/04/2024 at 3:10 pm confirmed that patient test reports did not list the laboratory name and address.

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:

. Based on record review and interview with the Laboratory Director, the laboratory failed to establish a written procedure for microscopic tissue examination for 11 (November 2023 - October 2024) of 11 months. Findings include 1. A review of the laboratory records revealed that the laboratory did not have a written procedure for microscopic tissue examination. 2. An interview on 11/04/2024 at 3:10 pm with the Laboratory Director confirmed that test procedures had not been established.

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The

laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Laboratory Director, the laboratory failed to document stain quality for Hematoxylin and Eosin (H&E) Staining for 6 (#1-6) of 6 patient test reports reviewed. Findings include: 1. A record review of 6 patients revealed that the stain quality for H&E staining was not documented for microscopic tissue examination: a. Patient 1: Tested on 10/31/2024 b. Patient 2: Tested on 9/26/2024 c. Patient 3: Tested on 7/3/2024 d. Patient 4: Tested on 5/30/2024 e. Patient 5: Tested on 2/27/2024 f. Patient 6: Tested on 11/16/2023 2. An interview was conducted on 11/04/2024 at 3:10 pm with the Laboratory Director confirmed that stain quality was not documented.

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 record review and interview with the Laboratory Director, the laboratory failed to document quality control for Immunohistochemistry (IHC) Positive and Negative controls for 6 (#1-6) of 6 patient test reports reviewed. Findings include: 1. A record review of 6 of 6 patients revealed IHC Positive and Negative controls were not documented: a. Patient 1: Tested on 10/31/2024 b. Patient 2: Tested on 9/26/2024 c. Patient 3: Tested on 7/3/2024 d. Patient 4: Tested on 5/30/2024 e. Patient 5: Tested on 2/27/2024 f. Patient 6: Tested on 11/16/2023 2. An interview was conducted on 11/04/2024 at 3:10 pm with the Laboratory Director revealed that IHC controls were not documented.

D5603

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

(b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under 493.1449(b), (l), or (m). (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Laboratory Director, the laboratory failed to retain slides for 5 (#2-6) of 6 patient test records reviewed. Findings include: 1. A record review revealed that the laboratory did not retain slides for the following patients: a. Patient 2: Tested on 9/26/2024 b. Patient 3: Tested on 7/3/2024 c. Patient 4: Tested on 5/30/2024 d. Patient 5: Tested on 2/27/2024 e. Patient 6: Tested on 11/16

/2023 2. An interview on 11/04/2024 at 3:10 pm with the Laboratory Director confirmed slides for patients listed above had not been retained.

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 record review and interview, the Laboratory Director failed to ensure a written procedure for microscopic tissue examination was established (refer to D5401), failed to ensure stain quality for Hematoxylin and Eosin (H&E) Staining was documented (refer to D5473), failed to ensure quality control for Immunohistochemistry (IHC) Positive and Negative controls was documented (refer to D5601), failed to ensure a quality assessment policy was established (refer to D6094), and failed to ensure retention of slides from microscopic tissue examination (refer to D5603).

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 reappoints 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:

. 1. Based on record review and interview with the Laboratory Director, the laboratory failed to retain slides for 5 (#2-6) of 6 patient test records reviewed. Refer to D5603.
2. Based on record review and interview, the Laboratory Director failed to ensure retention of patient slides for 5 (#2-5) of 6 records reviewed. Refer to D5603.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

. 1. Based on record review and interview, the Laboratory Director failed to ensure stain quality for Hematoxylin and Eosin Staining for 6 (#1-6) of 6 patient test reports

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| | <p>reviewed. Refer to D5473. 2. Based on record review and interview, the Laboratory Director failed to ensure quality control for Immunohistochemistry Positive and Negative controls were documented for 6 (#1-6) of 6 patient test reports reviewed. Refer to D5601</p> |
| D6094 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the laboratory failed to establish a quality assessment policy for 11 (November 2023 - October 2024) of 11 months. Findings include: 1. A record review revealed that the laboratory did not have a policy for quality assessment review. 2. An interview on 11/04/2024 at 3: 10 pm with the Laboratory Director confirmed that a competency assessment policy had not been established.</p> |
| D6106 | <p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14)</p> <p>The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview, the Laboratory Director failed to ensure a written procedure for microscopic tissue examination was established for 11 (November 2023 - October 2024) of 11 months. Refer to D5401.</p> |