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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 07D0099096 | (X3) Date Survey Completed 03/14/2022 |
| Name of Provider or Supplier Yale Dermatopathology Laboratory | Street Address, City, State 15 York Street Lci 504-505, New Haven, CT | |
| 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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| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to provide a written procedure manual that is signed and dated by the Laboratory Director (LD) before patient testing is performed. Findings include: 1. Record review on 03/14/2022 of the antibody validation binder revealed seven antibody (S100, S0X10, M5TF, HPV Low, HPV High, CK 116, Ki67) validations that were not signed and dated by the approval pathologist, 2 (HPV Low, HPV High) of which were already in use for patient testing. 2. Record review on 03/14/2022 of the laboratory procedure manual revealed no written procedure for the newly validated antibodies for the Immunohistochemistry antibody staining. 3. Staff interview on 03/14/2022 at 12:20 PM with the Laboratory Manager confirmed the above findings. 4. The laboratory performs 7,360 IHC tests annually in the specialty of pathology.</p> |
| D5407 | <p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on record review, surveyor observation and staff interview, the laboratory</p> |

failed to provide an updated written procedure manual that is signed and dated by the Laboratory Director (LD) before use. Findings include: 1. Record review on 03/14/2022 of the 'H&E Staining Sakura Prisma-G2 Combo' Version 002 procedure with a publish date of October 2020 revealed the approval date of the procedure manual by the LD to be 02/16/2021. 2. Surveyor observation on 03/14/2022 of the H&E staining Sakura Prisma-G2 combo instrument revealed the laboratory staining program, however it was not documented in the procedure manual. 3. Staff interview on 03/14/2022 at 12:30 PM with the Laboratory Manager confirmed that the laboratory updated the procedure manual to include the staining program, but never had the LD sign and date the updated procedure manual.

D5411

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(a)

Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to follow manufacturer's recommended temperature storage criteria in the specialty of pathology for the period of January 2020 through December 2020. Findings include: 1. Record review on 03/14/2022 of the 'Refrigerator Temperature Maintenance Log' for the period of January 2020 through December 2020 revealed the following: a. Acceptable temperature range for refrigerator 5850 in 2020 was 3 to 10 Degrees Celsius. b. Based on the package insert of the reagents stored in that refrigerator, the recommended storage temperature is between 2 to 8 degrees Celsius. c. Corrective action was not documented for 58 of 255 working days when the refrigerator temperature was outside of the range in 1b above. 2. Staff interview on 3/14/2022 at 11:15 AM with the Laboratory Manager verified the following: a. The 3 to 10 Degrees acceptable temperature range for refrigerator 5850 in 2020 was a typo. b. The acceptable established temperature range for refrigerator 5850 in 2020 was 3 to 5 Degrees Celsius.

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to provide evidence of monitoring and documenting humidity requirements and room temperature. Findings include: 1. Record review on 03/14/2022 of the laboratory maintenance folders for the years 2020 and 2021 revealed no documentation of humidity levels and

room temperature were recorded for either year. 2. Record review on 03/14/2022 of the 'Leica CM1850UV Cryostat Instructions for Use V1.5 RevG 10/2012' manual revealed the following: a. The acceptable air humidity is lower than 60%. b. The operating temperature range (ambient temperature) is 18 to 35 degrees Celsius. 3. Staff interview on 03/14/2022 at 11:05 AM with the Laboratory Manager confirmed the above findings.

D5481

CONTROL PROCEDURES
CFR(s): 493.1256(f)(g)

(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to document corrective action when temperatures exceeded established acceptable ranges in the specialty of pathology for the period of January 2021 through December 2021. Findings include: 1. Record review on 03/14/2022 of the 'Refrigerator Temperature Maintenance Log' for the period of January 2021 through December 2021 revealed the following: a. Acceptable temperature range for refrigerator 5850 in 2021 was 3 to 5 Degrees Celsius. b. Corrective action was not documented for 71 of 243 working days when the refrigerator temperature was outside of the range in 1a above. 2. Staff interview on 3/14/2022 at 11:15 AM with the Laboratory Manager verified the following: a. Acceptable temperature range for refrigerator 5850 in 2021 was 3 to 5 Degrees Celsius. b. The temperatures were out of range and documentation of corrective action was not recorded.

D6096

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(7)

The laboratory director must ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance characteristics are identified.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Laboratory Director (LD) failed to ensure that all necessary remedial actions were taken and documented when the temperature was out of range for the refrigerator in the specialty of pathology. Findings include: 1. Record review on 03/14/2022 of the Quality Assurance procedure revealed that the Director's must "Monitor Quality Control for the laboratory to determine if actual or potential problems exist with procedures or equipment. Works with lab manager to promptly initiate corrective action." 2. Record review on 03/14/2022 of the 'Refrigerator Temperature Maintenance Logs' for the period of January 2020 through December 2021 revealed that the LD failed to review and sign off on the maintenance logs. 3. Staff interview on 3/14/2022 at 11:20 AM with the Laboratory Manager confirmed the above findings.