

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  07D2067401	<b>(X3) Date Survey Completed</b>  03/08/2022
<b>Name of Provider or Supplier</b>  Milford Molecular Diagnostics, Llc	<b>Street Address, City, State</b>  2044 Bridgeport Ave, Milford, CT	
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>D5217</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy of the SARS-CoV-2 molecular test twice annually in the the subspecialty of Virology. Findings include: 1. Record review on 3/8/2022 of the laboratory's 'Molecular Diagnostic Test for SARS-CoV-2 in Cellular Components of Nasopharyngeal Swab Rinses by Nested RT-PCR followed by Sanger Sequencing for variant diagnosis' revealed in Section 17: "CAP SARS-CoV-2 proficiency test materials not compatible with Sanger sequencing assay .... Due to the synthetic RNA fragments used as proficiency test materials, which were designed to endorse the commercial RT-qPCR tests for SAR-CoV-2, and the results generated by RT-qPCR tests under EUA cannot be used as the reference materials or comparators for evaluation of the results achieved by Sanger sequencing". 2. Record review on 3/8/2022 of the College of American Pathologists SARS-CoV-2 Molecular COV2 participant evaluation reports for 2021 revealed: a. Three samples each were evaluated for both COV2-A and COV2-B events. b. Laboratory results received for 6 of 6 samples were resulted as indeterminate with grades of acceptable. c. Both evaluation reports were signed by the laboratory director with the following handwritten comment "The CAP materials are not compatible with Sanger sequencing methodology." 3. Staff interview on 3/8/2022 at 1:00 PM confirmed that the CAP survey material is not compatible with Sanger sequencing and that the laboratory did not verify the accuracy of their molecular SARS-CoV-2 assay by an alternate process. 4. The laboratory performs five tests annually in the subspecialty of Virology.</p>
<b>D5301</b>	TEST REQUEST

CFR(s): 493.1241(a)

The laboratory must have a written or electronic request for patient testing from an authorized person.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to ensure an authorized provider for SARS- CoV- 2 testing was mandated on the laboratory requisition in the subspecialty of Virology. Findings include: 1. Record review on 3/8 /2022 of the laboratory's web address, <http://dnalymetest.com/> revealed: a. Online requisition for 'Routine Partial N Gene Sanger Sequencing for SARS-CoV-2 Detection and Reflex Target S gene Sanger Sequencing for Determination of Variants of Concern and Interest' listed 'healthcare provider (optional)'. 2. Staff interview on 3/8 /2022 at 11:00 AM with the laboratory director (LD) confirmed the above. The LD was unaware that all test request must be from an authorized person. 3. The laboratory performs five tests annually in the subspecialty of Virology.

**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 staff interview, the laboratory failed to ensure the date and time of collection and specimen type appear on the specimen requisition. Findings include: 1. Record review on 3/8/2022 of the laboratory's SARS-CoV-2 requisition form revealed the date and time of collection and the specimen type were not solicited. 2. Staff interview with the laboratory director on 3/8/2022 at 11:00 AM confirmed the above findings. 3. The laboratory performs five tests annually in the subspecialty of Virology.

**D5311**

**SPECIMEN SUBMISSION, HANDLING, AND REFERRAL**

CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and

rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to ensure specimens received follow the established storage requirements during transportation for the SARS-CoV-2 specimens. Findings include: 1. Record review on 3/8/2022 of the laboratory's 'Molecular Diagnostics Test for SARS-CoV-2 in Cellular Components of Nasopharyngeal Swab Rinses by Nested RT-PCR Followed By Sanger Sequencing for Variant Diagnosis' procedure revealed: a. " Store specimens at 2-8 degree Celsius and ship overnight delivery to the lab on ice pack. If a specimen is frozen at minus 70 degrees Celsius, ship overnight to the lab on dry ice." 2. Record review on 3/8/2022 of the laboratory's web address, <http://dnalymetest.com/> revealed: a. "Ship the sample on the same day via FEDEX next morning delivery on a working day (not on Holidays or weekends) to Milford Molecular Diagnostics Laboratory" b. A link to the FEDEX web address, <https://www.fedex.com/en-us/shipping/how-to-ship-clinical-samples.html>. 3. Record review on 3/8/2022 of the FEDEX link from 2b above revealed the lack of storage or transport temperature requirements for SARS-CoV-2 clinical specimens. 4. The laboratory performs five tests annually in the subspecialty of Virology.

**D5403**

**PROCEDURE MANUAL**

CFR(s): 493.1251(b)

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.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory failed to provide a complete procedure manual in the subspecialty of Virology. Findings include: 1. Record review of laboratory's 'Molecular Diagnostics Test for SARS-CoV-2 in Cellular Components of Nasopharyngeal Swab Rinses by Nested RT-PCR Followed By Sanger Sequencing for Variant Diagnosis' procedure on 3/8/2022 revealed the following: Section 13: DNA Sequencing, Subsection A: Cycle Sequencing: did not contain step by step instructions for the Big Dye cycle sequencing program located in the Thermocycler. 2.

Staff interview with the laboratory director on 3/8/2022 at 3:30 PM confirmed the above mentioned procedure did not contain complete step by step instructions. 3. The laboratory performs five SARS-CoV-2 tests annually in the subspecialty of Virology.

**D5407**

**PROCEDURE MANUAL**  
CFR(s): 493.1251(d)

Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory director (LD) failed to ensure an approved laboratory procedure was in place prior to performing SARS-CoV-2 testing on patient samples in the subspecialty of Virology. Findings include: 1. Record review on 3/8/2022 of the laboratory's 'Molecular Diagnostics Test for SARS-CoV-2 in Cellular Components of Nasopharyngeal Swab Rinses by Nested RT-PCR Followed By Sanger Sequencing for Variant Diagnosis' procedure revealed the procedure was signed and approved by the LD on 4/15/2021. 2. Record review on 3/8/2022 of the laboratory's patient logs for SARS-CoV-2 testing revealed the laboratory performed testing and reported a SARS-CoV-2 patient result of negative on 8/6/2020. 3. Staff interview with the LD on 3/8/2022 at 1:22 PM confirmed the above findings.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:

Based on lack of documentation, record review and staff interview, the laboratory failed to verify the test performance of the laboratory developed SARS-CoV-2 molecular test when introducing a new specimen type in the subspecialty of Virology. Findings include: 1. Record review on 3/8/2022 of the laboratory's web address, <http://dnalymetest.com/> revealed: a. A mid-turbinate specimen is an acceptable specimen type for laboratory's SARS-CoV-2 testing. b. Instructions to self-collect a mid-turbinate specimen for SARS-CoV-2 by DNA sequencing. 2. Record review on 3/8/2022 of the laboratory's 'Molecular Diagnostic Test for SARS-CoV-2 in Cellular Components of Nasopharyngeal Swab Rinses by Nested RT-PCR followed by Sanger Sequencing for Variant Diagnosis' procedure revealed: a. Mid-turbinate specimens are not listed as an acceptable specimen type. 3. Staff interview on 3/8/2022 at approximately 9:45 AM with the laboratory director (LD): a. Confirmed the laboratory's website mentioned above listed mid-turbinate as an acceptable specimen for SARS-CoV-2 testing. b. Confirmed the laboratory's SARS-CoV-2 procedure,

signed by the laboratory director on 4/15/2021 lists nasopharyngeal swabs are the only acceptable specimen type. c. The laboratory did not have documentation for the validation of performance specifications for the mid-turbinate specimen type listed as acceptable in 1a above. 4. The laboratory performs five SARS-CoV-2 tests annually in the subspecialty of Virology.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on surveyor observation, record review and staff interview the laboratory failed to document routine maintenance and function checks for laboratory equipment in the subspecialty of Virology. Findings include: 1. Surveyor observation on 3/8/2022 at 2:00 PM of the laboratory revealed: a. A Labconco Purifier Biological Safety Cabinet (BSC) used to process samples for SARS-CoV-2 testing in use in the laboratory. b. An inspection sticker with a date of 4/21/2020 as the last date the BSC was inspected and certified. 2. Record review on 3/8/2022 of the laboratory's equipment maintenance records revealed the laboratory did not have maintenance and function check records for the above BSC. 3. Review of the 'Labconco Technical Manual', Section 2, Safety Precautions revealed, " The cabinet should be recertified whenever it is relocated, serviced or at least annually thereafter." 4. Staff interview with the laboratory director (LD) on 3/8/2022 at 2:30 PM: a. Confirmed the laboratory failed to have the above BSC serviced after 4/21/2020. b. The LD was unaware the above BSC should be recertified annually. 5. The laboratory performs five SARS-CoV-2 tests annually in the subspecialty of Virology.

**D5787**

**TEST RECORDS**

CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to ensure that corrections to laboratory records were properly noted and corrections appropriately documented in the subspecialty of Virology. Findings include: 1. Record review on 3/8/22 of a laboratory workbook containing handwritten test records for Human Papillomavirus testing on 12/21/2020 revealed: a. Whiteout was used to correct records of test date; specimen and control identification and placement; master mix reagent calculations and run start time. b. The whiteout covered the original records resulting in lack of documentation of the incorrect information, the date it was corrected and the initials of the person making the corrections. 2. Staff interview with testing personnel #1 (TP#1) on 3/8/22 at 1:56 PM confirmed the above noted

workbook belonged to TP#1 and he/she was unaware that the use of whiteout was prohibited.