Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D1063835	(X3) Date Survey Completed 06/04/2020
Name of Provider or Supplier Millennium Medical Corp	**Street Address, City, State** 13168 Centerpointe Way, Suite #101, Woodbridge, VA	

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 unannounced, on-site CLIA complaint survey was conducted at Millennium Medical Corp-Woodbridge on May 27, 2020 and off-site complaint surveys were conducted on May 28, 2020, and June 1 to June 4, 2020 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiencies are as follows:
D1000	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(c) Certificate of waiver tests. A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others: (1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following: (i) Bilirubin; (ii) Glucose; (iii) Hemoglobin; (iv) Ketone; (v) Leukocytes; (vi) Nitrite; (vii) pH; (viii) Protein; (ix) Specific gravity; and (x) Urobilinogen. (2) Fecal occult blood; (3) Ovulation tests-visual color comparison tests for human luteinizing hormone; (4) Urine pregnancy tests - visual color comparison tests; (5) Erythrocyte sedimentation rate-non-automated; (6) Hemoglobin-copper sulfate-non-automated; (7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use; (8) Spun microhematocrit; and (9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout. This STANDARD is not met as evidenced by: A. Based on document review and interviews, the laboratory performed high complexity testing for eight (8) patients utilizing the RayBiotech Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method) Test not authorized under the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver from April 20, 2020 to April 23, 2020. The findings

include: 1. Review of the laboratory's invoices from DxAllergy Solutions revealed the purchase of one (1) case of "Rapid Covid-19 Test" on April 11, 2020. 2. Review of the instructions for use (IFU) for the RayBiotech Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method) test revealed the statement, "This test has not been reviewed by the FDA." 3. Review of the laboratory's CMS ASPEN WEB-116 revealed the laboratory possesses a CLIA Certificate of Waiver. 4. On June 2, 2020, a review of the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) "In Vitro Diagnostics EUA" website revealed no listing for an EUA granted for the RayBiotech Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method) test. Review of the "FDA Frequently Asked Questions (FAQs) on Testing for SARS-CoV-2" website revealed the following: "Manufacturers that have notified FDA that they have validated and intend to distribute serology tests as set forth in Section IV.D: Manufacturer and Test-RayBiotech Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method) Test; Authorization Status-Not FDA authorized; Settings for use-H; Settings for use include the following: H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform high complexity tests..." 5. Review of patient test logs revealed the laboratory tested eight (8) patients using the RayBiotech Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method) test between April 20, 2020 and April 23, 2020. 6. In an exit interview on June 4, 2020 at 9:40 AM, the Chief Executive Officer (CEO) and Lab Director (LD) confirmed the above findings. B. Based on documentation review and interviews, the laboratory performed high complexity testing for forty-one (41) patients utilizing the BB Rapid-TQ Coronavirus (SARS-Co-V-2) Test Kits (Lateral flow method) not authorized under the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver from April 24, 2020 to May 5, 2020. The findings include: 1. Review of the laboratory's Boston BioPharma invoices revealed the purchase of ten (10) BB Rapid-TQ Coronavirus (SARS-Co-V-2) Test Kits (Lateral flow method) on 04/16/2020. 2. Review of the IFU for the Boston Biopharma BB Rapid-TQ Novel Coronavirus (SARS-CoV-2) Test revealed the statement, "This test has not been reviewed by the FDA." 3. Review of the laboratory's CMS ASPEN WEB-116 revealed the laboratory possesses a CLIA Certificate of Waiver. 4. On June 2, 2020, review of the "FDA EUA In Vitro Diagnostics EUA", website revealed no listing for the Boston Biopharma BB Rapid-TQ Novel Coronavirus (SARS-CoV-2) Test Kit (Lateral Flow method). Review of the "FDA FAQs on Testing for SARS-CoV-2" website revealed the following: a. A statement "Manufacturers that have notified FDA that they have validated and intend to distribute serology tests as set forth in Section IV.D." b. No listing for Boston Biopharma BB Rapid-TQ Novel Coronavirus (SARS-CoV-2) Test Kit (Lateral Flow method). 5. Review of patient test logs revealed the laboratory tested forty-one (41) patients using the BB Rapid-TQ kit between April 24, 2020 and May 5, 2020. 6. Review of a letter from the laboratory's attorney, dated June 1, 2020, revealed a statement, "In early May, 2020, Boston Biopharma issued an email to MMC [Millennium Medical Corp], stating that one of the tests purchased, the BB-TQ test, was being recalled due to complaints of inaccuracy. MMC immediately informed staff to not use the test any further. They then made plans to return all unused tests. With no information provided about any issues with the BB Rapid-MT tests, MMC began using that test, alone, from that point forward." In a phone interview on June 4, 2020 at approximately 9:40 AM, the CEO stated the laboratory received a letter from Boston Biopharma. A review of the letter revealed the following statement: "This is to inform you of a product recall involving: BB Rapid-TQ Coronavirus (SARS-CoV-2) Test kit (Lateral flow method) Catalog#: BB/RAPID-TQ Lot #: W1950030 This recall has been initiated since some of the

	customers that used tests from the above-mentioned lot number have informed us that the test kits are not functioning as expected." 7. In an exit interview on June 4, 2020 at approximately 9:40 AM, the CEO and LD confirmed the above findings. C. Based on a laboratory tour, document review, and interviews, the laboratory performed high complexity testing for one hundred twenty (120) patients utilizing the Boston Biopharma BB Rapid-MT Novel Coronavirus (SARS-CoV-2) Combined IgG/IgM Antibody Detection Kit (Colloidal Gold) not authorized under the laboratory's Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver from April 24, 2020 to May 26, 2020. The findings include: 1. During a tour of the laboratory on May 27, 2020 at approximately 9:15 AM, the surveyor observed a test kit labeled "Boston Biopharma BB Rapid-MT Novel Coronavirus (SARS-CoV-2) Combined IgG/IgM Antibody Detection Kit (Colloidal Gold)" with five (5) "IgG/IgM test pouches" remaining in the box. The box label read "Contents: 20 IgG/IgM pouches ... Lot number: 0414202955 expiration date: April 6, 2021, Storage conditions: 4-30 degrees Celsius." 2. Review of the manufacturer's IFU for the Boston Biopharma BB Rapid-MT Novel Coronavirus (SARS-CoV-2) Combined IgG/IgM Antibody Detection Kit (Colloidal Gold) revealed the statement "This test has not been reviewed by the FDA." 3. Review of the laboratory's ASPEN WEB-116 revealed the laboratory possesses a CLIA Certificate of Waiver. 4. On June 2, 2020, a review of the FDA EUA "In Vitro Diagnostics EUA" website revealed no listing for an EUA granted for the Boston Biopharma BB Rapid-MT Novel Coronavirus (SARS-CoV-2) Combined IgG/IgM Antibody Detection Kit. Review of the "FDA FAQs (Frequently Asked Questions) on Testing for SARS-CoV-2" website revealed the following: "Manufacturers that have notified FDA that they have validated and intend to distribute serology tests as set forth in Section IV.D: Manufacturer and Test-Boston Biopharma Inc. BB Rapid-MT; Authorization Status-Not FDA authorized; Settings for use-H; Settings for use include the following: H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, that meet requirements to perform high complexity tests..." 5. Review of the laboratory's Boston BioPharma invoices revealed the following BB Rapid-MT Coronavirus (SARS-Co-V-2) IgG/IgM Antibody Detection Kits (Colloidal Gold) purchases: five (5) kits purchased on 04/16/2020 and twenty (20) kits purchased on 05/21/2020. 6. Review of patient test logs revealed the laboratory tested one hundred and twenty (120) patients using the BB Rapid-MT kit between April 24, 2020 and May 26, 2020. 7. In an interview on May 27, 2020 at approximately 9:15 AM with the Site Manager (SM), the SM stated that they were using the BB Rapid-MT test kit for CoVID-19 testing since the end of April. 8. In a phone interview on May 27, 2020 at approximately 9:30 AM with the LD and CEO, the CEO stated they were using kits manufactured by BioPharma to perform patient CoVID-19 serologic testing. 9. In an exit interview on June 4, 2020 at 9:40 AM, the CEO and LD confirmed the above findings.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: A. Based on a review of patient test logs, lack of laboratory temperature and humidity logs, manufacturer's instructions for use (IFU) and interviews, the laboratory failed to

follow manufacturer's IFU for the storage of RayBiotech Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method) Test from April 11, 2020 until April 23, 2020. Findings include: 1. Review of the laboratory's invoices from DxAllergy Solutions revealed the purchase of one (1) case of "Rapid Covid-19 Test" on April 11, 2020. 2. A review of the laboratory's patient test logs revealed, the laboratory performed patient testing using the RayBiotech Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method) Test from April 20, 2020 until April 23, 2020, testing eight (8) patients. 3. A review of the IFU for the RayBiotech Novel Coronavirus (SARS-CoV-2) IgM Antibody Detection Kit (Colloidal Gold Method) Test revealed, "Keep kits in a cool and dry place at 2-30 degrees Celsius." 4. During a telephone interview with the Chief Executive Officer (CEO) at approximately 9:00 AM on May 28, 2020 the CEO stated they did not take temperatures of the area where the kits were stored. The surveyor requested temperature and humidity logs from April 11, 2020 to April 23, 2020. The laboratory provided no documentation of the temperature and humidity logs. 5. An exit interview with the Laboratory Director and CEO on June 4, 2020 at 9:40 AM confirmed the above findings. B. Based on a review of patient test logs, lack of laboratory temperature and humidity logs, manufacturer's instructions for use (IFU) and interviews, the laboratory failed to follow manufacturer's IFU for the storage of BB Rapid-TQ Coronavirus (SARS-Co-V-2) Test Kits (Lateral flow method) from April 16, 2020 until May 5, 2020. Findings include: 1. Review of the laboratory's Boston BioPharma invoices revealed the purchase of ten (10) BB Rapid-TQ Coronavirus (SARS-Co-V-2) Test Kits (Lateral flow method) on 04/16/2020. 2. A review of the laboratory's patient test logs revealed, the laboratory performed patient testing using the BB Rapid-TQ Coronavirus (SARS-Co-V-2) Test Kits (Lateral flow method) from April 24, 2020 until May 5, 2020, testing forty-one (41) patients. 3. A review of the IFU for the BB Rapid-TQ test kit revealed "Storage and Stability- 1. Storage at 2-30 degrees Celsius up to the expiration date printed on the package ...2. Keep away from sunlight, moisture and heat." 4. During a telephone interview with the CEO at approximately 9:00 AM on May 28, 2020 the CEO stated they did not take temperatures of the area where the kits were stored. The surveyor requested temperature and humidity logs from April 16, 2020 to May 5, 2020. The laboratory provided no documentation of the temperature and humidity logs. 5. An exit interview with the LD and CEO on June 4, 2020 at 9:40 AM confirmed the above findings. C. Based on a tour of the laboratory testing area, lack of laboratory temperature and humidity logs, manufacturer's instructions for use (IFU) and an interview, the laboratory failed to follow manufacturer's IFU for the storage of Boston Biopharma BB Rapid-MT Novel Coronavirus (SARS-CoV-2) Combined IgG/IgM Antibody Detection Kit (Colloidal Gold) from April 16, 2020 until May 27, 2020. Findings include: 1. During a tour of the laboratory on May 27, 2020 at approximately 9:15 AM, the surveyor observed a test kit labeled "Boston Biopharma BB Rapid-MT Novel Coronavirus (SARS-CoV-2) Combined IgG/IgM Antibody Detection Kit (Colloidal Gold)" with five (5) "IgG/IgM test pouches" remaining in the box. The box label read "Contents: 20 IgG/IgM pouches ... Lot number: 0414202955 expiration date: April 6, 2021, Storage conditions: 4-30 degrees Celsius." 2. Review of the laboratory's Boston BioPharma invoices revealed the following BB Rapid-MT Coronavirus (SARS-Co-V-2) IgG/IgM Antibody Detection Kits (Colloidal Gold) purchases: five (5) kits purchased on 04/16/2020 and twenty (20) kits purchased on 05/21/2020. 3. A review of the laboratory's patient test logs revealed, the laboratory performed patient testing using the BB Rapid-MT Novel Coronavirus (SARS-CoV-2) Combined IgG/IgM Antibody Detection Kit (Colloidal Gold) from April 24, 2020 until May 26, 2020, testing one hundred twenty (120) patients 4. A review of the IFU for the BB Rapid-MT test kit revealed "Storage and Expiration-Keep kits in a cool and dry place at 4-30

	degrees Celsius." 5. During a telephone interview with the CEO at approximately 9:00 AM on May 28, 2020 the CEO stated they did not take temperatures of the area where the kits were stored. The surveyor requested temperature and humidity logs from April 16, 2020 to May 27, 2020. The laboratory provided no documentation of the temperature and humidity logs. 6. An exit interview with the Laboratory Director and CEO on June 4, 2020 at 9:40 AM confirmed the above findings.