

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2204961	(X3) Date Survey Completed 05/31/2023
Name of Provider or Supplier Assurance Lab Works, Llc	Street Address, City, State 3306 Hwy 377 E, Granbury, 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	The laboratory was surveyed in response to complaint TX00457380 for compliance with CMS 42CFR regulations. Complaint TX00457380 was substantiated.
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: I. Based on direct observation, review of manufacturer's instructions and confirmed in interview, the laboratory failed to ensure 1 of 1 lot of expired BD Veritor System For Rapid Detection of Flu A and B was not available for use in patient testing. Findings Included: 1. During a tour of the facility on 05/31/2023 at 10:05 a.m., the surveyor observed the following in the facility storage room (Room 1): 1 box (kit) of BD Veritor System For Rapid Detection of Flu A and B Kit Lot: 0003731 Kit Expiration Date: 12/19/2022 2. Review of manufacturer's instructions for the BD Veritor System For Rapid Detection of Flu A and B (Rev 2017-10) kit revealed the following: "Warnings and Precautions ..7. Do not use kit components beyond the expiration date" 3. During an interview on 05/31/2023 at 10:10 a.m., the office manager stated the kits in the storage area were used for testing, but was unable to provide the patient test logs. This confirmed the above findings. II. Based on direct observation and confirmed in interview, the laboratory failed to ensure 1 of 1 lot of expired Single Slide Fecal Occult Blood Test devices was not available for use in patient testing. Findings Included: 1. During a tour of the facility on 05/31/2023 at 10:05 a.m., the surveyor observed the following in the facility storage room (room 1): 1 box (kit) of Single Slide Fecal Occult Blood Test Kit Lot: 0419238 Kit Expiration Date: 08/31 /2021 2. During an interview on 05/31/2023 at 10:10 a.m., the office manager stated the kits in the storage area were used for testing, but was unable to provide the patient</p>

test logs. This confirmed the above findings. III. Based on direct observation and confirmed in interview, the laboratory failed to ensure 1 of 1 lot of expired Drugscan Blood Kit was not available for use in patient testing. Findings Included: 1. During a tour of the facility on 05/31/2023 at 10:15 a.m., the surveyor observed the following in the facility storage room located on the shelf in one cardboard box (room 1): 10 boxes of Drugscan Blood Kit Kit Lot: MANBX10000125 Kit Expiration Date: 06/30/2022 2. During an interview on 05/31/2023 at 10:10 a.m., the office manager stated the kits in the storage area were used for testing, but was unable to provide the patient test logs. This confirmed the above findings. IV. Based on direct observation and confirmed in interview, the laboratory failed to ensure 1 of 1 lot of expired EDTA tubes was not available for use in patient testing. Findings Included: 1. During a tour of the facility on 05/31/2023 at 10:15 a.m., the surveyor observed the following in the facility storage room located in a black bin, in a large plastic bag (room 1): 16 EDTA Purple Tubes Lot: 1319208 Expiration Date: 02/28/2023 2. During an interview on 05/31/2023 at 10:10 a.m., the office manager stated the kits in the storage area were used for testing, but was unable to provide the patient test logs. This confirmed the above findings. V. Based on direct observation, final patient reports and confirmed in interview, the laboratory failed to ensure 1 of 1 lot of expired Healgen One Step Rapid Test for COVID-19 cassettes was not available for use in patient testing. Findings Included: 1. During a tour of the facility on 05/31/2023 at 10:20 a.m., the surveyor observed the following in the facility patient draw room located on the sample processing table (room 2): 8 Healgen One Step Rapid Test for COVID-19 Test Cassettes Kit Lot: 2004173 Kit Expiration Date: 04/2022 2. Review of patient records revealed the following patients tested for rapid COVID-19 beyond the cassettes expiration date: a. Date performed: 07/22/2022 Patient Date of Birth (DOB): 01/28/1949 Results of rapid test: Negative b. Date performed: 12/05/2022 Patient Date of Birth (DOB): 12/21/57 Results of rapid test: Negative c. Date performed: 12/14/2022 Patient Date of Birth (DOB): 05/28/1960 Results of rapid test: Negative d. Date performed: 12/15/2022 Patient Date of Birth (DOB): 04/04/1961 Results of rapid test: Negative e. Date performed: 03/02/2023 Patient Date of Birth (DOB): 03/19/1959 Results of rapid test: Negative f. Date performed: 03/29/2023 Patient Date of Birth (DOB): 10/25/1968 Results of rapid test: Negative g. Date performed: 04/06/2023 Patient Date of Birth (DOB): 07/16/1988 Results of rapid test: Negative h. Date performed: 04/24/2023 Patient Date of Birth (DOB): 12/05/2005 Results of rapid test: Positive 3. During an interview on 05/31/2023 at 10:48 a.m. in the main facility waiting room, the office manager was asked if COVID-19 rapid tests were performed on patients with the cassettes in the patient draw room. The office manager confirmed the Healgen One Step Rapid Test for COVID-19 cassettes were used for patient testing. VI. Based on direct observation, final patient reports and confirmed in interview, the laboratory failed to ensure 1 of 1 lot of expired Healgen One Step Rapid Test for COVID-19 buffer reagent was not available for use in patient testing. Findings Included: 1. During a tour of the facility on 05/31/2023 at 10:20 a.m., the surveyor observed the following in the facility patient draw room located on the sample processing table (room 2): 2 bottles of Healgen One Step Rapid Test for COVID-19 buffer reagent Lot: 202005034 Expiration Date: 11/07/2022 2. Review of patient records revealed the following patients tested for rapid COVID-19 beyond the buffer expiration date: a. Date performed: 12/05/2022 Patient Date of Birth (DOB): 12/21/57 Results of rapid test: Negative b. Date performed: 12/14/2022 Patient Date of Birth (DOB): 05/28/1960 Results of rapid test: Negative c. Date performed: 12/15/2022 Patient Date of Birth (DOB): 04/04/1961 Results of rapid test: Negative d. Date performed: 03/02/2023 Patient Date of Birth (DOB): 03/19/1959 Results of rapid test: Negative e. Date performed: 03/29/2023 Patient Date of Birth (DOB): 10/25/1968 Results of rapid test: Negative f. Date performed: 04/06/2023 Patient Date of Birth

(DOB): 07/16/1988 Results of rapid test: Negative g. Date performed: 04/24/2023 Patient Date of Birth (DOB): 12/05/2005 Results of rapid test: Positive 3. During an interview on 05/31/2023 at 10:40 a.m. in the main facility waiting room, the office manager was asked if COVID-19 rapid tests were performed on patients with the supplies in the patient draw room. The office manager confirmed the Healgen One Step Rapid Test for COVID-19 kit supplies were used for patient testing. VII. Based on direct observation and confirmed in interview, the laboratory failed to ensure 2 of 2 lots of expired Sienna COVID-19 Rapid Antigen Control Swabs were not available for use in patient testing. Findings Included: 1. During a tour of the facility on 05/31/2023 at 10:26 a.m., the surveyor observed the following in the facility patient draw room located on the sample processing table (room 2): 2 swabs of Sienna COVID-19 Rapid Antigen Control Swabs a. 1 positive swab Lot: EE21100011-T Expiration Date: 10/21/2022 b. 1 negative swab Lot: 20211007 Expiration: 10/21/2022 2. During an interview on 05/31/2023 at 10:40 a.m. in the main facility waiting room, the office manager was asked if COVID-19 rapid tests were performed on patients with the supplies in the patient draw room. The office manager stated the supplies were used for patient testing. This confirmed the above findings. VIII. Based on direct observation and confirmed in interview, the laboratory failed to ensure 4 of 4 lots of expired COVID collection devices were not available for use in patient testing. Findings Included: 1. During a tour of the facility on 05/31/2023 at 10:36 a.m., the surveyor observed the following in the facility patient draw room located in a plastic cabinet under the sample processing table (room 2): COVID-19 Collection Kits a. Lot: 198802 Expiration: 06/07/2022 Number of collection kits: 2 b. Lot: 204797 Expiration: 06/10/2022 Number of collection kits: 8 c. Lot: 216619 Expiration: 06/29/2022 Number of collection kits: 4 d. Lot: 216678 Expiration: 07/03/2022 Number of collection kits: 9 2. During an interview on 05/31/2023 at 10:48 a.m. in the main facility waiting room, the office manager was asked if the COVID-19 collection kits were used to collect patient specimens for testing. The office manager stated the collection kits in the patient draw room were used for patient testing. This confirmed the above findings. IX. Based on direct observation and confirmed in interview, the laboratory failed to ensure 1 of 1 lot of expired QuantiFERON TB gold tubes were not available for use in patient testing. Findings Included: 1. During a tour of the facility on 05/31/2023 at 10:38 a.m., the surveyor observed the following in the facility patient draw room located in a plastic cabinet under the sample processing table (room 2): QuantiFERON TB Collection Kits Gold Sample Tubes located in kits Lot: A220136F Expiration: 04/30/2023 Number of collection kits: 8 2. During an interview on 05/31/2023 at 10:48 a.m. in the main facility waiting room, the office manager was asked if the collection kits were used to collect patient specimens for testing. The office manager stated the collection kits in the patient draw room were used for patient testing. This confirmed the above findings. Word Key EDTA- Ethylenediaminetetraacetic Acid COVID- Coronavirus Disease TB- Tuberculosis