Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0685447	(X3) Date Survey Completed 08/31/2023
Name of Provider or Supplier Corewell Health Dearborn Hospital Laboratory	**Street Address, City, State** 18101 Oakwood Boulevard, Dearborn, 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
D0000	The purpose of this unannounced survey was for complaint #MI00138851. The Department of Licensing and Regulatory Affairs has evaluated this facility and determined that it is not in compliance with CLIA regulations (42 CFR Part 93, effective April 24, 2003).
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: . Based on record review and interviews, the laboratory failed to follow its procedures for specimen rejection for 2 of 2 female specimens reviewed for Prostate Specific Antigen (PSA) testing (refer to D5311) and failed to follow its Prostate Specific Antigen (PSA) test procedure (refer to D5401).
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 interviews, the laboratory failed to follow its procedures for specimen rejection for 2 of 2 female specimens reviewed for Prostate Specific Antigen (PSA) testing. Findings include: 1. A review of two patient test requests and test reports revealed the following patients were indicated as female on the test request and had PSA testing reported: a. Patient 9943239 had PSA testing ordered on 8/1/23 and results reported on 8/3/23. b. Patient 7807018 had PSA testing ordered on 8/4/23 and results reported on 8/5/23. 2. A review of the laboratory's "Abbott Architect Immunoassay System Analyzer Operation" procedure revealed a section titled "Specimen Collection and Handling" stating, "Certify the correct specimen type is used. The ARCHITECT system does not verify specimen type." 3. A review of the laboratory's "Architect Total PSA" manufacturer's instructions for use revealed a section titled "Intended Use" stating, "The ARCHITECT Total PSA assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of Total PSA (both Free PSA and PSA complexed to alpha-1-antichymotrypsin) in human serum: a. As an aid in the detection of prostate cancer when used in conjunction with digital rectal exam (DRE) in men 50 years or older. Prostatic biopsy is required for diagnosis of cancer. b. As an adjunctive test to aid in the management of prostate cancer patients." 4. An interview on 8/31/23 at 10:50 am with the Technical Director for Clinical Chemistry revealed the only female patients PSA testing should be performed on is transgender females. 5. An interview on 8/31/23 at 11:19 am with the Laboratory Director revealed the laboratory did not have documentation showing these patients had been documented as transgender females and confirmed the specimens had not been rejected according to the laboratory's policies and procedures.
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 interviews, the laboratory failed to follow its Prostate Specific Antigen (PSA) test procedure for 2 of 2 female specimens with Prostate Specific Antigen (PSA) testing reviewed. Findings include: 1. A review of two patient test reports revealed the following patients were indicated as female on the test request and had PSA testing reported: a. Patient 9943239 had results reported on 8/3/23. b. Patient 7807018 had results reported on 8/5/23. 2. A review of the laboratory's "Architect Total PSA" manufacturer's instructions for use revealed a section titled "Intended Use" stating, "The ARCHITECT Total PSA assay is a Chemiluminescent Microparticle Immunoassay (CMIA) for the quantitative determination of Total PSA (both Free PSA and PSA complexed to alpha-1-antichymotrypsin) in human serum: a. As an aid in the detection of prostate cancer when used in conjunction with digital rectal exam (DRE) in men 50 years or older. Prostatic biopsy is required for diagnosis of cancer. b. As an adjunctive test to aid in the management of prostate cancer patients." 3. An interview on 8/31/23 at 10:50 am with the Technical Director for Clinical Chemistry revealed the only female patients PSA testing should be performed on is transgender females. 4. An interview on 8/31/23 at 11:19 am with the Laboratory Director revealed the laboratory did not have documentation showing these patients had been documented as transgender females and confirmed PSA testing on the

	patients listed above was not performed according to the laboratory's policies and procedures.
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 interviews, the Laboratory Director failed to ensure laboratory personnel followed procedures for specimen rejection for 2 of 12 female specimens reviewed for Prostate Specific Antigen (PSA) testing (Refer to D6087 A), failed to ensure laboratory personnel followed its Prostate Specific Antigen (PSA) test procedure for 2 of 2 female specimens with Prostate Specific Antigen (PSA) testing reviewed (Refer to D6087 B), failed to ensure the Clinical Consultant provided consultation regarding the appropriateness of ordering Prostate Specific Antigen (PSA) testing on female patient specimens (Refer to D6101 A) and failed to ensure testing personnel followed the laboratory's Prostate Specific Antigen (PSA) test procedure for 2 female specimens with Prostate Specific Antigen (PSA) testing (Refer to D6101 B).
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: . A. Based on record review and interview, the Laboratory Director failed to ensure laboratory personnel followed procedures for specimen rejection for 2 of 12 female specimens reviewed for Prostate Specific Antigen (PSA) testing. Refer to D5311. B. Based on record review and interview, the Laboratory Director failed to ensure laboratory personnel followed its Prostate Specific Antigen (PSA) test procedure for 2 of 2 female specimens with Prostate Specific Antigen (PSA) testing reviewed. Refer to D5401.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: . A. Based on record review and interview, the Laboratory Director failed to ensure the Clinical Consultant provided consultation regarding the appropriateness of ordering Prostate Specific Antigen (PSA) testing on female patient specimens. Refer

	to D6136. B. Based on record review and interview, the Laboratory Director failed to ensure testing personnel followed the laboratory's Prostate Specific Antigen (PSA) test procedure for 2 female specimens with Prostate Specific Antigen (PSA) testing. Refer to D6175.
D6134	CLINICAL CONSULTANT CFR(s): 493.1453 The laboratory must have a clinical consultant who meets the requirements of 493. 1455 of this subpart and provides clinical consultation in accordance with 493.1457 of this subpart. This CONDITION is not met as evidenced by: . . Based on record review and interview, the Clinical Consultant failed to provide consultation regarding the appropriateness of ordering Prostate Specific Antigen (PSA) testing on female patient specimens. Refer to D6136.
D6136	CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1457 The clinical consultant provides consultation regarding the appropriateness of the testing ordered and interpretation of test results. This STANDARD is not met as evidenced by: . Based on record review and interview with the Laboratory Director, the Clinical Consultant failed to provide consultation regarding the appropriateness of ordering Prostate Specific Antigen (PSA) testing on female patient specimens for 1 of 1 client the laboratory serves. Findings include: 1. A review of two patient test requests and test reports from one client referring testing revealed the following patients were indicated as female on the test request and had PSA testing reported: a. Patient 9943239 had PSA testing ordered on 8/1/23 and results reported on 8/3/23. b. Patient 7807018 had PSA testing ordered on 8/4/23 and results reported on 8/5/23. 2. An interview on 8/31/23 at 11:22 am with the Laboratory Director confirmed there was a lack of documentation of consultation with the Clinical Consultant regarding the appropriateness of PSA testing in female patients for the client requesting testing.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: . Based on record review and interview, testing personnel failed to follow its Prostate Specific Antigen (PSA) test procedure for 2 of 2 female specimens with Prostate Specific Antigen (PSA) testing. Refer to D6175.
D6175	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1495(b)(1)

	Each individual performing high complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: . Based on record review and interview, testing personnel failed to follow its Prostate Specific Antigen (PSA) test procedure for 2 of 2 female specimens with Prostate Specific Antigen (PSA) testing. Refer to D5401.