Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2126392	10/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
Modern Male T Clinic - Cypress	12361 Barker Cypress Road, Cypress, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the laboratory's policy, the analyzer's establishment verification records, IQCP records, the quality control records from November, 2023 to September 2024, patient reports, and confirmed in an interview, the laboratory failed to establish an IQCP to support the modification in quality control testing by following the manufacturer's instruction for two of two Fastpack IP Systems. The findings were: 1. The surveyor's direct observation on 10/03/2024 at 10: 15 am in the lab revealed the laboratory had 2 Fastpack IP Systems. SN: 0853 SN: 0405 2. Review of the laboratory's policy titled TAB 6: Performing the Test (Analytic Processes) under Individualized Quality Control Plan (IQCP) Instructions revealed "1. Perform QC daily for 10 business days during the initial period." 3. Review of the laboratory's CMS 116 application, signed by the LD on 09/23/2024, revealed the laboratory's business hours were Mondays to Saturdays. 4. Review of the laboratory's establishment verification records for the above two analyzers revealed the following:

	SN: 0853 LD signed off in December, 2022 SN: 0405 LD signed off in November, 2023 5. Further review of the laboratory's establishment verification records revealed the following: SN: 0853 QC ran from 12/05/2022 to 12/09/2022 (Total of 5 days) SN: 0405 QC ran from 11/01/2023 to 11/04/2023 and 11/06/2023 (Total of 5 days) Therefore, the laboratory failed to follow the manufacturer's instruction to run QC for 10 business days during the initial period for two of two Fastpack IP Systems. 6 In an interview on 10/03/2024 at 11:00 am in the break room, the testing personnel #1 confirmed the laboratory performed QC every 7 days. 7. Random review of the quality control records from November, 2023 to September 2024 revealed: SN: 0853 QC was performed on 11/01/2023 (Expired on 11/05/2023) 11/08/2023 (Expired on 11 /13/2023) 11/15/2023 (Expired on 11/20/2023) 11/22/2023 (Expired on 11/27/2023) 02/07/2024 (Expired on 02/12/2024) 02/12/2024 (Expired on 02/17/2024) 02/14/2024 (Expired on 02/19/2024) 02/21/2024 (Expired on 02/26/2024) 05/08/2024 (Expired on 05/13/2024) 05/15/2024 (Expired on 05/20/2024) 05/23/2024 (Expired on 05/28 /2024) 05/29/2024 (Expired on 06/02/2024) QC were missed on SN: 0853 11/06/2023 11/07/2023 11/14/2023 11/21/2023 02/20/2024 05/14/2024 05/21/2024 05/22/2024 SN: 0405 QC was performed on 12/27/2023 (Expired on 01/01/2024) 01/03/2024 (Expired on 01/08/2024) 01/09/2024 (Expired on 01/14/2024) 01/10/2023 (Expired on 01/15/2024) 01/17/2024 (Expired on 01/22/2024) 01/24/2024 (Expired on 01/29 /2024) 01/31/2024 (Expired on 02/04/2024) 02/07/2024 (Expired on 02/12/2024) 08 /28/2024 (Expired on 09/01/2024) 08/31/2024 (Expired on 09/04/2024) 09/04/2024 (Expired on 09/09/2024) 09/11/2024 (Expired on 09/16/2024) 09/19/2024 (Expired on 09/24/2024) QC were missed on SN: 0405 01/02/2024 01/16/2024 01/23/2024 01/30 /2024 02/05/2024 02/06/2024 09/10/2024 09/17/2024 09/18/2024 8/ Review patient reports for the above missed QC dates revealed: SN: 0853 11/06/2023 Patient DOB:12 /05/1988 11/07/2023 Patient DOB: 12/23/1981 11/14/2023 Patient DOB: 07/28/1978 11/21/2023 Patient DOB: 09/28/1986 02/20/2024 Patient DOB: 11/03/1964 05/14 /2024 Patient DOB: 03/19/1981 05/22/2024 Patient DOB: 12/31/1971 SN: 0405 01/02 /2024 Patient DOB: 08/19/1966 01/02/2024 Patient DOB: 08/19/1989 01/30/2024 Patient DOB: 02/26/1971 01/02/2024 Patient DOB: 08/19/1966 02/05/2024 Patient DOB: 10/24/1962 02/06/2024 Patient DOB: 08/31/1990 09/17/2024 Patient DOB: 01 /02/1977 09/18/2024 Patient DOB: 02/25/1983 9. In an interview on 10/03/2024 at 12: 10 pm in the break room, the testing personnel #1 confirmed the above findings. Key: IQCP=Individual Quality Control Plan LD=Laboratory Director QC=Quality Control
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the review of the laboratory's CMS 209 form, the personnel's training records, and confirmed in an interview, the laboratory failed to have a training documentation prior to patient testing for 1 of 2 testing personnel performing moderate complexity testing on Qualigen Fastpack IP system for testosterone test. The findings were: 1. The surveyor's direct observation on 10/03 /2024 at 10:15 am in the lab revealed the laboratory had 2 Qualigen Fastpack testing systems. SN: 0853 SN: 0405 2. Review of the laboratory's submitted CMS 209 form, Laboratory Personnel Report (CLIA), signed by the laboratory direction on 10/02 /2024, revealed the laboratory identified 2 testing personnel performed moderate complexity testing on Qualigen Fastpack IP system for testosterone test. 3. Review of

	the testing personnel's training record revealed no training documentation on Qualigen Fastpack IP system prior to patient testing. Testing personnel #2: Hired Date: August, 2024 as a full-time employee 4. An interview on 10/03/2024 at 2:51 pm in the break room, the testing personnel #1 confirmed the above findings.