Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2144442	**(X3) Date Survey Completed** 10/15/2024
Name of Provider or Supplier Houston Male Health Clinic Pllc	**Street Address, City, State** 5763 Fairmont Pkwy, Pasadena, 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 April 5, 2023 to May 31, 2023 and Januanry 3, 2024 to Feburary 28, 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 10/15/2024 at 10:15 am in the lab revealed the laboratory had 2 Fastpack IP Systems. SN: 0318 SN: 0440 2. Review of the laboratory's policy in Quality Assurance Manual titled TAB 6: Performing the Test (Analytic Processes) under Individualized Quality Control Plan (IQCP) Instructions (65000160 Rev 007 06 /15) 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 10/07/2024, 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: 0318 LD signed off in 2018 SN: 0440 LD signed off in December, 2021 5. Further review of the laboratory's establishment verification records revealed the following: SN: 0318 QC ran from 12/05/2022 to 12/07/2022 business days (Total of 3 days) SN: 0440 QC ran from 12/05/2022 to 12/07/2022 business days (Total of 3 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 10/15/2024 at 11:43 am in the end of the hallway, the techincal consultant confirmed the laboratory performed QC on Wednesdays (Every 7 days). 7. Random review of the quality control records from April 5, 2023 to May 31, 2023 and Januanry 3, 2024 to Feburary 28, 2024 revealed: SN: 0318 and SN: 0440 QC both were performed on 04/05/2023 (Expired on 04/07/2023) 04/12/2023 (Expired on 04/14/2023) 04/19/2023 (Expired on 04/21/2023) 04/26/2023 (Expired on 04/28/2023) 05/03/2023 (Expired on 05/05/2023) 05/10/2023 (Expired on 05/12/2023) 05/17/2023 (Expired on 05/19/2023) 05/24/2023 (Expired on 05/26/2023) 05/31/2023 (Expired on 06/02/2023) 01/03/2024 (Expired on 01/05/2024) 01/10/2024 (Expired on 01/12/2024) 01/17/2024 (Expired on 01/19/2024) 01/24/2024 (Expired on 01/26/2024) 01/31/2024 (Expired on 02/02/2024) 02/07/2024 (Expired on 02/09/2024) 02/14/2024 (Expired on 02/16/2024) 02/21/2024 (Expired on 02/23/2024) 02/28/2024 (Expired on 03/01/2024) QC were missed on SN: 0318 and SN: 0440 04/08/2023 04/10/2023 04/11/2023 04/15/2023 04/17/2023 04/18/2023 04/22/2023 04/24/2023 04/25/2023 04/29/2023 05/01/2023 05/02/2023 05/06/2023 05/08/2023 05/09/2023 05/13/2023 05/15/2023 05/16/2023 05/20/2023 05/22/2023 05/23/2023 05/27/2023 05/29/2023 05/30/2023 01/06/2024 01/08/2024 01/09/2024 01/13/2024 01/15/2024 01/16/2024 01/20/2024 01/22/2024 01/23/2024 01/27/2024 01/29/2024 01/30/2024 02/03/2024 02/05/2024 02/06/2024 02/10/2024 02/12/2024 02/13/2024 02/17/2024 02/19/2024 02/20/2024 02/24/2024 02/26/2024 02/27/2024 8/ Review patient reports for the above missed QC dates revealed 208 patients had testosterone tests on Fastpack Systems. SN: 0318 04/08/2023 MRN: 890684 04/08/2023 MRN: 890721 04/08/2023 MRN: 27054 04/10/2023 MRN: 26396 04/10/2023 MRN: 24838 04/10/2023 MRN: 25886 04/11/2023 MRN: 27112 04/11/2023 MRN: 11306 04/11/2023 MRN: 27121 04/11/2023 MRN: 26565 04/17/2023 MRN: 24654 04/18/2023 MRN: 26268 04/18/2023 MRN: 26844 04/18/2023 MRN: 27021 04/18/2023 MRN: 27192 04/18/2023 MRN: 27131 04/18/2023 MRN: 5724 04/19/2023 MRN: 25807 04/22/2023 MRN: 26499 04/22/2023 MRN: 27055 04/24/2023 MRN: 26874 04/24/2023 MRN: 27271 04/24/2023 MRN: 27150 04/24/2023 MRN: 12226 04/24/2023 MRN: 14563 04/25/2023 MRN: 12754 04/25/2023 MRN: 26057 04/25/2023 MRN: 14459 05/01/2023 MRN: 11577 05/01/2023 MRN: 20563 05/01/2023 MRN: 16673 05/01/2023 MRN: 19894 05/01/2023 MRN: 9700 05/02/2023 MRN: 25197 05/02/2023 MRN: 5909 05/02/2023 MRN: 27379 05/02/2023 MRN: 26332 05/06/2023 MRN: 27436 05/06/2023 MRN: 25337 05/06/2023 MRN: 27055 05/08/2023 MRN: 26252 05/08/2023 MRN: 25280 05/08/2023 MRN: 21160 05/09/2023 MRN: 26693 05/09/2023 MRN: 27459 05/09/2023 MRN: 20069 05/09/2023 MRN: 27469 05/13/2023 MRN: 26336 05/13/2023 MRN: 27484 05/13/2023 MRN: 27579 05/15/2023 MRN: 27383 05/15/2023 MRN: 27389 05/16/2023 MRN: 27469 05/16/2023 MRN: 22381 05/16/2023 MRN: 27519 05/20/2023 MRN: 7640 05/20/2023 MRN: 23145 05/20/2023 MRN: 9345 05/22/2023 MRN: 27602 05/22/2023 MRN: 27562 05/22/2023 MRN: 27611 05/22/2023 MRN: 27484 05/22/2023 MRN: 17571 05/23/2023 MRN: 11639 05/23/2023 MRN: 27624 05/23/2023 MRN: 27626 05/27/2023 MRN: 11507 05/27/2023 MRN: 11367 05/30/2023 MRN: 25994 05/30/2023 MRN: 26874 01/06/2024 MRN: 28568 01/06/2024 MRN: 30405 01/06/2024 MRN: 15413 01/08/2024 MRN: 30340 01/08/2024 MRN: 30416 01/08/2024 MRN: 17354 01/08/2024 MRN: 30418 01/08/2024 MRN: 24838 01/09/2024 MRN: 29711 01/09/2024 MRN: 28394 01/09/2024 MRN: 28152 01/09/2024 MRN: 28394 01/13/2024 MRN:

	29990 01/13/2024 MRN: 16976 01/13/2024 MRN: 21160 01/13/2024 MRN: 29205 01/13/2024 MRN: 30508 01/13/2024 MRN: 30506 01/15/2024 MRN: 30519 01/15/2024 MRN: 5875 01/15/2024 MRN: 30203 01/15/2024 MRN: 29504 01/16/2024 MRN: 21049 01/16/2024 MRN: 28232 01/16/2024 MRN: 30167 01/16/2024 MRN: 30340 01/16/2024 MRN: 29401 01/16/2024 MRN: 19174 01/16/2024 MRN: 5724 01/16/2024 MRN: 30340 01/16/2024 MRN: 29401 01/16/2024 MRN: 19174 01/20/2024 MRN: 30582 01/27/2024 MRN: 14390 01/20/2024 MRN: 14390 01/20/2024 MRN: 30582 01/22/2024 MRN: 30589 01/22/2024 MRN: 24654 01/22/2024 MRN: 25994 01/23/2024 MRN: 30544 01/23/2024 MRN: 11306 01/23/2024 MRN: 5909 01/23/2024 MRN: 21049 01/27/2024 MRN: 30694 01/27/2024 MRN: 23316 01/27/2024 MRN: 13776 01/27/2024 MRN: 30680 01/29/2024 MRN: 18842 01/29/2024 MRN: 25280 01/29/2024 MRN: 29481 01/29/2024 MRN: 15075 01/29/2024 MRN: 29050 01/29/2024 MRN: 9700 01/30/2024 MRN: 30662 01/30/2024 MRN: 30552 01/30/2024 MRN: 24618 01/30/2024 MRN: 18597 02/03/2024 MRN: 5430 02/03/2024 MRN: 14639 02/03/2024 MRN: 30693 02/05/2024 MRN: 16673 02/05/2024 MRN: 13959 02/05/2024 MRN: 30783 02/05/2024 MRN: 14325 02/05/2024 MRN: 14092 02/06/2024 MRN: 11151 02/06/2024 MRN: 25197 02/06/2024 MRN: 30800 02/06/2024 MRN: 30693 02/10/2024 MRN: 19879 02/10/2024 MRN: 30741 02/10/2024 MRN: 30784 02/12/2024 MRN: 9163 02/12/2024 MRN: 15369 02/12/2024 MRN: 15341 02/12/2024 MRN: 29445 02/13/2024 MRN: 23923 02/13/2024 MRN: 29743 02/13/2024 MRN: 30892 02/13/2024 MRN: 30552 02/19/2024 MRN: 8778 02/19/2024 MRN: 29838 02/19/2024 MRN: 30800 02/20/2024 MRN: 28383 02/20/2024 MRN: 29003 02/24/2024 MRN: 30203 02/24/2024 MRN: 15299 02/24/2024 MRN: 31028 02/26/2024 MRN: 9321 02/26/2024 MRN: 12122 02/26/2024 MRN: 29449 02/27/2024 MRN: 21049 02/27/2024 MRN: 29711 SN: 0440 04/08/2023 MRN: 14172 04/08/2023 MRN: 27092 04/08/2023 MRN: 9345 04/18/2023 MRN: 6989 04/18/2023 MRN: 22399 04/18/2023 MRN: 27107 04/24/2023 MRN: 14325 04/24/2023 MRN: 13641 05/01/2023 MRN: 27351 05/01/2023 MRN: 16085 05/02/2023 MRN: 23545 05/02/2023 MRN: 26889 05/06/2023 MRN: 26446 05/13/2023 MRN: 8778 05/13/2023 MRN: 27518 05/20/2023 MRN: 27561 05/20/2023 MRN: 12067 05/22/2023 MRN: 14092 05/23/2023 MRN: 9321 05/27/2023 MRN: 27661 05/27/2023 MRN: 16367 01/06/2024 MRN: 30403 01/08/2024 MRN: 30417 01/08/2024 MRN: 5929 01/08/2024 MRN: 30345 01/13/2024 MRN: 6095 01/13/2024 MRN: 5465 01/15/2024 MRN: 29244 01/18/2024 MRN: 25886 01/16/2024 MRN: 25500 01/16/2024 MRN: 26768 01/20/2024 MRN: 30506 01/27/2024 MRN: 30139 01/27/2024 MRN: 22677 01/27/2024 MRN: 30600 01/29/2024 MRN: 10728 01/29/2024 MRN: 23846 01/30/2024 MRN: 28238 02/05/2024 MRN: 13641 02/10/2024 MRN: 7189 02/10/2024 MRN: 28442 02/12/2024 MRN: 30345 02/19/2024 MRN: 28680 02/24/2024 MRN: 28455 02/27/2024 MRN: 30544 9. In an interview on 10/15/2024 at 2:00 pm in the end of hallway, the technical consultant confirmed the above findings. Key: IQCP=Individual Quality Control Plan LD=Laboratory Director QC=Quality Control MRN=Medical Record Number