

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2187903	(X3) Date Survey Completed 02/07/2025
Name of Provider or Supplier Total Md Physician Group Pllc	Street Address, City, State 202 Industrial Blvd, Ste 501, Sugar Land, 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	A recertified survey was completed on 02/07/2025. 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.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's direct observation, the review of the manufacturer's user guide, CMS 116 application, the laboratory's room temperature and humidity logs in June 2023 and September 2024 for POST-PCR Room 2, patient results, and confirmed in an interview, the laboratory failed to have correct acceptable temperature and humidity ranges according to the manufacturer's user guide for 43 of 43 days reviewed of temperature and 39 of 43 days of humidity reviewed for 1 of 6 instruments: Agena MassArray System in Post-PCR Room 2. The findings were: 1. The Surveyor's direct observation on 02/06/2025 at 9:10 am during the lab tour revealed the following instruments in Post-PCR Room 2. Biorad CFX OPUS 96 RT-PCR System (SN: 795 BR 04398) Biorad CFX OPUS 384 RT-PCR System (SN: 796 BR 02641) Agena MassArray System (SN: PR2101924/CP2107578) Applied Biosystems Veriti 96-Well Thermal Cycler (SN: 2990246422) Applied Biosystems</p>

Veriti 96-Well Thermal Cycler (SN: 2990244525) Applied Biosystems Veriti 96-Well Thermal Cycler (SN: 2990244510) 2. Review of the manufacturer's user guide titled Mass ARRAY System with Chip Prep Module 96 User Guide by Agena Bioscience (Doc. USG-CUS-069 R09) under Chapter 1 Introduction of Table 1.9 Environmental Requirements revealed "Temperature 16-24C (61-75F) Humidity 30-75% relative humidity" 3. Review of the laboratory's room temperature and humidity log revealed the laboratory defined "Temperature Range (15C)-(30C) Humidity Range (30%)-(80%)." 4. Review of the laboratory's CMS 116 application, the laboratory director signed on 12/30/2024, revealed Agena MassArray performed PGX tests and NGX tests. 5. Random review of the laboratory's room temperature and humidity logs in June 2023 and September 2024 for POST-PCR Room 2 revealed the Post-PCR Room 2 had 42 of 43 days of temperature and 39 of 43 days of humidity reviewed were out of ranges. 06/01/2023 Temperature 26C Humidity 26% 06/02/2023 Temperature 25C Humidity 26% 06/03/2023 Temperature 26C Humidity 26% 06/05/2023 Temperature 24C 06/06/2023 Temperature 25C 06/07/2023 Temperature 26C Humidity 26% 06/08/2023 Temperature 25C Humidity 29% 06/09/2023 Temperature 26C Humidity 26% 06/10/2023 Temperature 27C Humidity 27% 06/12/2023 Temperature 25C Humidity 26% 06/13/2023 Temperature 25C Humidity 25% 06/14/2023 Temperature 26C Humidity 26% 06/15/2023 Temperature 26C Humidity 23% 06/16/2023 Temperature 27C Humidity 24% 06/17/2023 Temperature 27C Humidity 28% 06/19/2023 Temperature 27C Humidity 28% 06/20/2023 Temperature 27C Humidity 28% 06/21/2023 Temperature 27C Humidity 23% 06/22/2023 Temperature 26C Humidity 23% 06/23/2023 Temperature 26C Humidity 23% 06/24/2023 Temperature 27C Humidity 27% 06/26/2023 Temperature 28C Humidity 21% 06/27/2023 Temperature 28C Humidity 21% 06/28/2023 Temperature 26C Humidity 23% 06/29/2023 Temperature 26C Humidity 23% 06/30/2023 Temperature 26C Humidity 23% 09/02/2024 Temperature 26C Humidity 25% 09/03/2024 Temperature 27C Humidity 25% 09/04/2024 Temperature 27C Humidity 25% 09/05/2024 Temperature 26C Humidity 25% 09/06/2024 Temperature 26C Humidity 26% 09/09/2024 Temperature 27C Humidity 26% 09/10/2024 Temperature 27C Humidity 25% 09/11/2024 Temperature 28C Humidity 25% 09/12/2024 Temperature 28C Humidity 25% 09/13/2024 Temperature 28C Humidity 25% 09/16/2024 Temperature 28C Humidity 25% 09/17/2024 Temperature 28C Humidity 25% 09/18/2024 Temperature 28C Humidity 25% 09/19/2024 Temperature 27C Humidity 25% 09/20/2024 Temperature 27C Humidity 26% 09/23/2024 Temperature 28C Humidity 25% 09/24/2024 Temperature 28C Humidity 25% 09/25/2024 Temperature 28C Humidity 26% 09/26/2024 Temperature 28C Humidity 26% 09/27/2024 Temperature 27C Humidity 27% 09/30/2024 Temperature 28C Humidity 24% 6. Review patient results for the above dates revealed 34 patients had PGX and NGX testing. 06/07/2023 19 PGX testing Sample ID: 41220840303010 Sample ID: 41220840303120 Sample ID: 41220840303101 Sample ID: 41220840303152 Sample ID: 41220840303099 Sample ID: 41220840303100 Sample ID: 41220613310740 Sample ID: 41220840303154 Sample ID: 41220851703105 Sample ID: 41220840303153 Sample ID: 41220840303124 Sample ID: 41220840303098 Sample ID: 41220840303119 Sample ID: 41220840404020 Sample ID: 41220840303137 Sample ID: 41220840303139 Sample ID: 41220840303138 Sample ID: 41220840303033 Sample ID: 41220840303014 09/17/2024 7 PGX testing Sample ID: IGL240002214 Sample ID: IGL240002215 Sample ID: IGL240002216 Sample ID: IGL240002220 Sample ID: IGL240002225 Sample ID: IGL240002179 Sample ID: 41231150108154 09/19/2024 5 NGX testing Sample ID: 41231150108194 Sample ID: 41240350414343 Sample ID: 41240350414533 Sample ID: 41240350414621 Sample ID: 41231150108206 09/23/2024 3 PGX testing Sample ID: IGL240002215 Sample ID: IGL240002220 Sample ID: IGL240002225 7. An interview on 02/07/2025 at 10:50 am in the Inventory & QA room, the general

supervisor (as indicated on the CMS 209 form) confirmed the above finding. Key: C=Celsius F=Fahrenheit CMS=Center for Medicare and Medicaid Services

D5785

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(3)

(b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's room temperature and humidity logs for Post-PCR room 2 in September 2024, the laboratory's records, patient results, and confirmed in an interview, the laboratory failed to have documentation of corrective actions for 21 of 21 days reviewed when the humidity was out of laboratory defined ranges. The findings were: 1. Review of the laboratory's room temperature and humidity log under Daily Temperature revealed " ...If the temperature or humidifies are out of range, notify supervisor and document corrective action" 2. Further review of the laboratory's room temperature and humidity log revealed "Temperature Range (15C)-(30C) Humidity Range (30%)-(80%)." 3. Random review of the laboratory's room temperature and humidity logs for Post-PCR Room 2 in September 2024 revealed 21 of 21 days humidity reviewed was out of laboratory defined ranges. 09/02/2024 25% 09/03/2024 25% 09/04/2024 25% 09/05/2024 25% 09/06/2024 26% 09/09/2024 26% 09/10/2024 25% 09/11/2024 25% 09/12/2024 25% 09/13/2024 25% 09/16/2024 25% 09/17/2024 25% 09/18/2024 25% 09/19/2024 25% 09/20/2024 26% 09/23/2024 25% 09/24/2024 25% 09/25/2024 26% 09/26/2024 26% 09/27/2024 27% 09/30/2024 24% 4. Review the patient results for the dates above revealed 15 patients had testing performed in Post-PCR Room 2. 09/17/2024 Sample ID: IGL240002214 09/17/2024 Sample ID: IGL240002215 09/17/2024 Sample ID: IGL240002216 09/17/2024 Sample ID: IGL240002220 09/17/2024 Sample ID: IGL240002225 09/17/2024 Sample ID: IGL240002179 09/17/2024 Sample ID: 41231150108154 09/19/2024 Sample ID: 41231150108194 09/19/2024 Sample ID: 41240350414343 09/19/2024 Sample ID: 41240350414533 09/19/2024 Sample ID: 41240350414621 09/19/2024 Sample ID: 41231150108206 09/23/2024 Sample ID: IGL240002215 09/23/2024 Sample ID: IGL240002220 09/23/2024 Sample ID: IGL240002225 5. Review of the laboratory's records revealed no documentation of corrective actions for the above days when humidity were out of laboratory defined ranges. 6. In an interview on 02/07/2025 at 10:50 am in the Inventory & QA room, the general supervisor (as indicated on the CMS 209 form) confirmed the above finding. Key: C=Celsius F=Fahrenheit CMS=Center for Medicare and Medicaid Services