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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D2131556 | (X3) Date Survey Completed 07/10/2018 |
| Name of Provider or Supplier The Medical Resort At Willowbrook | Street Address, City, State 13220 Breton Ridge Street, Houston, 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 |
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| D0000 | The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D8100 - 42 C.F.R. 493.1771 Condition: Inspection requirements applicable to all CLIAcertified and CLIA-exempt laboratories. Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit. |
| D8100 | <p>INSPECTION REQUIREMENTS CFR(s): 493.1771</p> <p>Each laboratory issued a CLIA certificate must meet the requirements in 493.1773 and the specific requirements for its certificate type, as specified in 493.1775 through 493.1780. All CLIA-exempt laboratories must comply with the inspection requirements in 493.1773 and 493.1780, when applicable.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory records and confirmed in interview, the laboratory failed to meet the requirements in 493.1773. Refer to D8103</p> |
| D8103 | <p>BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d)</p> <p>(b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not</p> |

limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part.

This STANDARD is not met as evidenced by:

Based on review of the facility's CMS116 application, surveyor observations, laboratory records and laboratory supplies, and confirmed in interview, the laboratory was not ready to perform non-waived arterial blood gas (ABG) testing as of the date of the survey on 07/10/18. No instrumentation or supplies, test procedures, or training of testing personnel were available for review. Findings were: 1. A review of the CMS116 initial application for a certificate of compliance was signed on 02/20/17. The CMS116 application was entered into the CLIA database on 06/01/17 and this was the effective date of the CLIA certificate of registration. 2. A review of the CMS116 application indicated the laboratory would perform ABG patient testing with the specialty and subspecialty of general chemistry for an annual total volume of 2000; and waived PT (Protime) and glucose patient testing for an annual volume 20000. 3. During a tour of the facility on 07/10/18 at 0925 hours revealed the facility only performed waived glucose testing using Evencare G2 glucose meters; no instrumentation or supplies to perform nonwaived ABG patient testing were available for review. 5. Attempted review of the facility procedures for ABG testing revealed no proficiency testing records or personnel training records available for review as of the date of survey on 07/10/18. 6. An interview with the respiratory director on 07/10/18 at 0940 hours in the nurse's station confirmed the above findings. She stated that she has never ordered nor has she ever performed ABG testing at the facility. She stated that she nor her staff had been trained at the facility to perform ABG testing. She acknowledged that the facility had not enrolled in proficiency testing. The laboratory was not ready to perform nonwaived ABG patient testing as of the date of the survey on 07/10/18. key: CMS - Centers of Medicare and Medicaid Services