Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2141019	07/12/2018
Name of Provider or Supplier	**Street Address, City, State**	
Forward Hcg Pearland Llc Dba Thrive Rehabilitation	3406 Business Center Dr, Pearland, 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	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	INSPECTION REQUIREMENTS CFR(s): 493.1771 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. 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
D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (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

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 07/12/18. No 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 08/29/17. The signature on the CMS116 application was not legible. The CMS116 application was entered into the CLIA database on 12/5/17 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 10000. 3. A tour of the facility on 07/12/18 at 0930 hours revealed the facility only performed waived glucose patient testing using Evencare G2 glucose meters and PT patient testing using the Coaguchek XS. 4. 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 07/12/18. 5. An interview with the executive director in the reception area on 7/12/18 at 0945 hours revealed the facility received an iSTAT analyzer on 07/10/18 via a courier sent by the VP (vice president) of operations. The executive director stated that he stored it in his office. He acknowledged that the iSTAT analyzer (SN 371131) had no base unit, manual, or procedures. He stated that he has never ordered nor has he ever performed ABG testing on the analyzer. He acknowledged that the facility had not enrolled in proficiency testing nor had any supplies to perform nonwaived ABG testing for the iSTAT analyzer. The laboratory was not ready to perform nonwaived ABG patient testing as of the date of the survey on 07/12/18. 6. Review of patient records from 2018 revealed the facility began waived patient testing on 02/2018. Review of the iSTAT analyzer memory provided by the executive director revealed 43 patient IDs from 06/2017 to 12/2017 for Creatinine (CRS) prior to the facility effective date of the CLIA certificate on 12/5/17. Date Patient ID Analyte Result (mg/dL) 12/08/17 1406263 CRS 0.80 11/28/17 1392811 CRS 0.60 11/09/17 558365 CRS 0.90 11/08/17 790330 CRS 1.10 11/04/17 1402503 CRS 0.70 10/26/17 1400025 CRS 1.00 10/19/17 1397114 CRS 0.80 10/18/17 498233 CRS 0.80 10/16/17 1384817 CRS 0.80 10/12/17 937185 CRS 1.20 10/11/17 1300288 CRS 0.70 10/10/17 1100830 CRS 0.80 09/29/17 534559 CRS 0.60 09/28/17 1391446 CRS 1.30 09/27/17 1316153 CRS 1.00 09/26/17 1332292 CRS 1.20 09/26/17 1366659 CRS 0.70 09/22/17 1256224 CRS 1.00 09/21/17 1134053 CRS 1.00 09/20/17 513305 CRS 1.20 09/16/17 549855 CRS 0.60 09/14/17 1385336 CRS 0.90 09/14/17 943898 CRS 0.80 09/13/17 759219 CRS 1.40 09/12/17 1385701 CRS 0.90 09/12/17 no ID CRS 1.30 09/01/17 1329673 CRS 1.20 08/22/17 1290266 CRS 0.80 08/10/17 1112396 CRS 1.30 08/01/17 1377398 CRS 0.70 07/26/17 1376430 CRS 1.00 07/21/17 1349471 CRS 0.90 07/20/17 1344908 CRS 0.70 07/19/17 2070974 CRS 0.90 07/12/17 975042 CRS

	0.90 07/07/17 721051 CRS 1.10 07/05/17 1336529 CRS 0.60 06/30/17 569484 CRS 1.00 06/28/17 1368801 CRS 0.90 06/27/18 1368731 CRS 0.90 06/23/17 980357 CRS 0.90 06/21/17 1367454 CRS 0.90 06/21/17 1366659 CRS 0.80 7. Review of the patient data on the iSTAT analyzer revealed the patient ID and/or test date did not correspond to patient IDs or date of service from the patients in the facility. 8. An interview with the director of nursing on 07/12/18 at 1000 hours confirmed the above findings. She stated that since she started working at the facility, the facility had never performed ABG patient testing. Furthermore, after her own review of the patient IDs from the iSTAT analyzer memory confirmed that the patient ID numbers were not the same used by the facility. key: CMS - Centers of Medicare and Medicaid Services