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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D2017356 | (X3) Date Survey Completed 05/15/2018 |
| Name of Provider or Supplier Altus Baytown Hospital | Street Address, City, State 1626 W Baker Road, Baytown, 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 representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. |
| D1001 | <p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory test results, and confirmed in interview, the laboratory failed to follow manufacturer's instructions to confirm preliminary positive drug screen results using the CLIA waived Integrated E-Z Split Key Cup II. 1. A review of the package insert for the Integrated E-Z Split Key Cup II (DN: 1156117001, effective 3/16/17) revealed "This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result." 2. Random review of drug screen laboratory test results from 10/2017 to 03/2018 revealed 6 of 7 patient results with test results as preliminary positive (POS) with no documentation of confirmatory results. date ACT Number Results 10/03/17 24617 Benzodiazepines - POS 11/14/17 25206 Opiates - POS; THC -POS; Oxycodone - POS 12/05/17 25206 Opiates - POS 01/03/18 TC 04/1/70 Benzodiazepines - POS; Opiates - POS; Methamphetamine - POS; Amphetamine - POS 02/13/18 26361 Benzodiazepines - POS; THC - POS; Opiates - POS; Oxycodone 03/10/18 21792 Benzodiazepines - POS; Opiates - POS; Methadone - POS 3. An interview with the technical consultant on 05/10/18 at 1150</p> |

hours in the conference room confirmed the above findings. She was aware that the preliminary positive results needed to be sent out for confirmation. She is working with the facility to find a laboratory to perform the confirmation. key: THC - Tetrahydrocannabinol POS - positive

D2087

ROUTINE CHEMISTRY

CFR(s): 493.841(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's American Proficiency Institute (API) Chemistry proficiency testing records from 2016, and staff interview, the laboratory failed to attain a satisfactory score of at least 80% for the analyte pO2. The findings were: 1. A review of the laboratory's API from 2016 revealed the laboratory failed to attain a satisfactory score of at least 80% for the analytes pO2 on 1 of 3 events: 2016 Event 3 pO2 (60%) lab result acceptable result IB12 116 45 - 90 IB13 135 59-96 2. An interview with the technical consultant on 5/15/18 at 1015 hours in the conference room confirmed the above findings.