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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D2050604 | (X3) Date Survey Completed 10/31/2018 |
| Name of Provider or Supplier Healthcare Express | Street Address, City, State 106 South Oop 59, Atlanta, 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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| D5401 | <p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: . Based on review of laboratory policy for cardiac enzyme testing using the Alere Triage Cardiac Panel, confirmed by staff interview, the laboratory failed to follow its own policy for periodic review of the individual quality control plan (IQCP) developed for the system. Findings: 1. Laboratory policies were reviewed. Included was an IQCP section for the Alere Triage Cardiac Panel dated 04-22-15, which contained a sheet titled "IQCP Review Policy" in which was stated the following: "The IQCP and the Quality Control Plan will be reviewed annually in the month of June. The monthly quality control results for the past 12 months along with the results of the last 3 Proficiency Testing events will be reviewed to ensure that the QC plan is sufficient to ensure quality patient results. Any corrections needed will be implemented." 2. Also included was a sheet titled "Triage Quality Assurance," documenting the initial review dated 06-06-2016, signed by the technical consultant (CMS form 209). No documentation of IQCP review for 2017 or 2018 was found. In an interview at the site on 10-31-2018 the technical consultant confirmed that no such documentation could be made available during the survey.</p> |