| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 34D0239689 | 01/09/2019 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Planned Parenthood South Atlantic - Chapel Hill | 1765 Dobbins Drive, Chapel Hill, NC | |

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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| **D3031** | RETENTION REQUIREMENTS<br>CFR(s): 493.1105(a)(3)<br><br>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory procedure, review of 2017 and 2018 quality control records, and interview with nursing director 01/09/19, the laboratory failed to retain all Rh(D) quality control records for at least two years. Review of laboratory procedure "PREPARATION OF RH CONTROLS" revealed the statement; "Use the Antigram Antigen Profile (Panoscreen Masterlist) to identify the positive and negative controls....We are required to maintain the Panoscreen Antigram Antigen Profile sheets for two years. They will be maintained in the QA/QC Binder." Review of quality control records revealed the laboratory failed to retain copies of the manufacturer's assay sheets for the following lot numbers of Panoscreen cells: 1. #49126, expiration 02/09/18 2. #5129, expiration 04/06/18 Interview with nursing director at approximately 2:00 p.m. confirmed the assay sheets were missing. She stated the facility was not retaining the assay sheets as required in 2018 and she thought they had printed out all that were missing." |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. |

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| | This STANDARD is not met as evidenced by:<br>Based on review of 2017 and 2018 quality control (QC) records, review of Panoscreen assay sheets, review of patient testing logs and review of CMS-116 form 01/09/19, the laboratory failed to discard control materials that had exceeded their expiration date and performed testing on patient specimens when control materials were expired. Patient testing logs for 2017 were printed alphabetically, not by date of testing, surveyor was unable to determine exactly how many patients were affected each day in 2017 that expired control materials were used. Review of CMS-116 submitted at time of survey revealed 2,377 Rhesus Factor D (Rh D) tests are performed annually. QC records indicate testing was performed approximately 4 days a week or approximately 208 days a year. The number of patients tested daily is approximately 11. Review of Rh Control Log, Panoscreen assay sheets and patient testing logs revealed the following: 1. Panoscreen Lot #01882, expiration 03/10/17, was used on 03/11/17. Approximately 11 patients were affected. 2. Panoscreen Lot #25162, expiration 08/25/17, was used on 08/26/17. Approximately 11 patients were affected. 3. Panoscreen Lot #33255, expiration 10/20/17, (the incorrect expiration date of 10/23 /17 was entered on Rh Control Log), was used on 10/21/17. Approximately 11 patients were affected. 4. Panoscreen Lot #45080, expiration 01/12/18, was used on 01 /13/18. 18 patients were affected. |
| **D6021** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(5)<br><br>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory quality assessment (QA) policies, review of quality assessment records and deficiencies cited at time of survey 01/09/19, the laboratory director failed to ensure the laboratory's quality assessment program was maintained to identify and correct problems and assure the quality of laboratory services. The laboratory quality assessment policies revealed on Page 17 of procedure manual "Quality Assessment Task List...1. By the 15th day of the following month, daily, weekly, and monthly RQM tasks are reviewed by the Health Center Manager for completeness and accuracy with results documented on the HCM RQM Checklist (RQM 03).". 1. Review of monthly "HCM RQM Checklist (RQM 03)" for 2017 and 2018 revealed the reviews failed to identify and correct problems found at time of survey (see D5417 and D3031). 2. Review of laboratory quality assessment form "Lab Director Quarterly Review" for 2017 and 2018 revealed "Logs Reviewed: ....RQM 58 (Eldon Cards)...". The quarterly reviews failed to identify and correct problems with Rh Controls for Eldon Cards found at time of survey (see D5417). |