

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0920474	(X3) Date Survey Completed 01/10/2018
Name of Provider or Supplier Advanced Reproductive Health Centers Chicago Ivf	Street Address, City, State 10811 W 143rd St Ste 120, Orland Park, IL	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory records and interview with the laboratory technical supervisor (TS) #2; the laboratory failed to establish policies and procedures to assess employee competency. Findings Include: 1. Review of the laboratory's policy and procedure manual found no policy had been established to assess the competency of personnel listed on the CMS-209 which include the technical supervisors, general supervisors, clinical consultants and testing personnel. 2. On survey date 01-10-2018 at 11:20am TS#2 confirmed the laboratory had failed to establish a competency assessment policy.</p>
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with technical supervisor (TS) #2; the laboratory's technical supervisors failed to ensure annual competency</p>

assessments were completed for 2 of 2 testing personnel. Findings Include: 1. Review of competency assessment records for testing personnel (TP) #1 and TP#2 from 2016 through 2017 found that semen analysis competency assessments were not completed in 2016 and 2017 for TP#2 and in 2017 for TP#1. 2. During survey date 01-10-2018, at 11:20 am, the surveyor's findings were confirmed by TS#2.