Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D1100176	03/28/2019
Name of Provider or Supplier	**Street Address, City, State**	
Cellular Technology Limited	20521 Chagrin Blvd, Shaker Heights, OH	

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
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based upon a record review and an interview with the Director of Regulatory Affairs, the Laboratory Director (LD) failed to specify the duties and responsibilities of 4 out of 4 Technical Supervisors (TS), and 1 out of 1 General Supervisor (GS) listed on the CMS-209. Findings include: 1. Review of the CMS-209 form found 4 individuals listed as performing duties of a TS, and 1 individual listed as performing duties of a GS. 2. Review of policies and procedures failed to find evidence that the duties and responsibilities of the TS and the GS were specified in writing by the laboratory director. 3. An interview with the Director of Regulatory Affairs, on 3/28/19 at 11:12 am, confirmed that the LD failed to specify the duties and responsibilities of the TS and GS in writing.