

## Revisions to Form CMS-209, Laboratory Personnel Report (CLIA)

Section # on CMS-209	Type of Change	Reason for the Change
2. CLIA Identification Number	Move the number 2. to the correct box.	Formatting
5. Telephone	Remove 5. Telephone section.	Information already on CMS 116
Page 1 4. Instructions:	Update 4. Instructions for the Laboratory -List below all personnel with responsibilities for testing in the last two years. -Do not list personnel that only perform specimen processing, clerical functions, waived or not testing. -Use a separate line for personnel performing more than one CLIA position. For moderate complexity testing, list the positions of D, CC, TC and TP. For high complexity testing, list the positions of D, CC, TS, GS and TP. For cytology, list D, CC, TS, CT/GS and CT. -Check the appropriate column for each position held. For TC and TS use the number that corresponds with the specialty areas of responsibility. Refer to the <b>SPECIALTY LIST on page 2.</b> -Indicate each individual's highest level of qualification: Use (M) for moderate and (H) for high complexity. -Only one person may be listed as the laboratory director.	Clarify/simplify instructions.
Page 1 For Official Use Only	Gray out both boxes. Move from the top box to the second box: Qualifications according to Subpart M	To clarify visually the official use only sections.
Page 1 Section 4 Positions Held	Added (M) for moderate or (H) for high complexity after position titles. TC – Technical Consultant (M) TS – Technical Supervisor (H) GS – General Supervisor (H)	Clarify/simplify instructions.
Page 1	Update the abbreviation of Laboratory Director from D to LD	Consistency with other documents.
Page 1 Row with a. and b.	Remove the row with a. and b. above columns.	No longer needed with new instructions.
Page 1 Hover bubbles in blank boxes for positions held	Update the numbering of specialties for TC and TS.	Clarify and match directions on page 2
Page 1 Positions held boxes	Allow only one checkmark or number for a row.	Assist with instructions.
Page 1 under Certification	Remove the comma after "qualify".	Grammar
Page 2 Instructions	Update instruction. For the positions of Technical Consultant (TC) and Technical Supervisor (TS): Use the following SPECIALTY LIST to	Clarify/simplify instructions.

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	<p>indicate the specialty areas of responsibility for the TC and/or TS. Record the number corresponding to the specialty in the appropriate TC or TS column. When one or more individuals function as a TC or TS in more than one specialty or subspecialty, use a separate line for each.</p>	
Page 2 GRID:	Replace the word GRID with SPECIALTY LIST.	Clarify
Page 2 GRID:	<p>Remove regulatory citations</p> <ol style="list-style-type: none"> <li>1. Bacteriology</li> <li>2. Mycobacteriology</li> <li>3. Mycology</li> <li>4. Parasitology</li> <li>5. Virology</li> <li>6. Diagnostic Immunology</li> <li>7. Chemistry</li> <li>8. Hematology</li> <li>9. Immunohematology</li> <li>10. Radiobioassay</li> <li>11. Cytology</li> <li>12. Histopathology</li> <li>13. Dermatopathology</li> <li>14. Ophthalmic Pathology</li> <li>15. Oral Pathology</li> <li>16. Histocompatibility</li> <li>17. Clinical Cytogenetics</li> </ol>	<p>The current version of the <a href="#">CMS-209</a> lists technical supervisor regulatory citations, whereas this section of the form is intended for both technical supervisor and technical consultant. We believe this adds confusion. Further, we believe surveyors have other resources available (e.g. <a href="#">eCFR</a>, <a href="#">QSEP</a>) to assist with the regulatory citations needed to complete the Official Use Only portion of the form.</p>
Page 2 EXAMPLE	Update the table example with additional personnel.	Clarify
Page 2 EXAMPLE	<p>Under the table in the example, add:  In this example, John Smith is the TC for Microbiology and the TS for Hematology and Jane Cook is the TS for Immunohematology.</p>	Additional vocabulary to help explain the usage of table.
Page 2 FOR OFFICIAL USE ONLY	Add: QUALIFICATIONS ACCORDING TO SUBPART M	To correspond with page 1.
Page 2 FOR OFFICIAL USE ONLY (gray area)	<p>Update cytology supervisor to cytology general supervisor.  Update cytotechnologist to cytotechnologists.</p>	<p>To correspond with page 1.  Clarify.</p>
Page 2 Expiration Date: 4/30/2025	Change expiration date to xx/xx/xxxx until approved.	
Footer:	Update date (9/2024)	

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FORM CMS-209 (01/2021)		