

(For moderate and high complexity testing)

1. LABORATORY NAME		2. CLIA IDENTIFICATION NUMBER	
3. LABORATORY ADDRESS (<i>NUMBER AND STREET</i>)	CITY	STATE	ZIP CODE

- 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 no testing.
- Use a separate line for personnel holding more than one CLIA position.
 - For moderate complexity testing, list the positions of LD, CC, TC and TP.
 - For high complexity testing, list the positions of LD, CC, TS, GS and TP.
 - For cytology, list LD, 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 SPECIALTY LIST on page 2.
- 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.

LD - Laboratory Director
CC - Clinical Consultant
TC - Technical Consultant (M)
TS - Technical Supervisor (H)
GS - General Supervisor (H)
TP - Testing Personnel
CT/GS - Cytology General Supervisor
CT - Cytotechnologist

FOR OFFICIAL USE ONLY
(NOT TO BE COMPLETED BY LABORATORY)

DATE OF SURVEY _____

[illegible]

READ THE FOLLOWING CAREFULLY BEFORE SIGNING

Statement or Entities Generally: Whoever, in any manner within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact, or makes false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious or fraudulent statements or entry, shall be fined not more than \$10,000 or imprisoned not more than five years, or both. (U.S. Code, Title 18, Sec. 1001)

CERTIFICATION: I CERTIFY THAT ALL OF THE INDIVIDUALS LISTED ABOVE QUALIFY TO FUNCTION IN THE POSITION INDICATED, ACCORDING TO THE PERSONNEL REGULATIONS OF 42 CFR PART 493 SUBPART M.

5. SIGNATURE OF LABORATORY DIRECTOR	
6. PRINTED NAME OF LABORATORY DIRECTOR	7. DATE

INSTRUCTIONS FORM CMS-209

This form will be completed by the laboratory. It will be used by the surveyor to review the qualifications of technical personnel in the laboratory.

For the positions of Technical Consultant (TC) and Technical Supervisor (TS):

Use the following SPECIALTY LIST to 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.

SPECIALTY LIST

- | | |
|--------------------------|---------------------------|
| 1. Bacteriology | 10. Radiobioassay |
| 2. Mycobacteriology | 11. Cytology |
| 3. Mycology | 12. Histopathology |
| 4. Parasitology | 13. Dermatopathology |
| 5. Virology | 14. Ophthalmic Pathology |
| 6. Diagnostic Immunology | 15. Oral Pathology |
| 7. Chemistry | 16. Histocompatibility |
| 8. Hematology | 17. Clinical Cytogenetics |
| 9. Immunohematology | |

EXAMPLE

In the example below, John Smith is the TC for Hematology and the TS for Bacteriology. Jane Cook is the TS for Immunohematology.

EMPLOYEE NAMES			POSITION HELD								M OR H	QUALIFICATIONS ACCORDING TO SUBPART M
LAST NAME	FIRST NAME	MI	LD	CC	TC	TS	GS	TP	CT/GS	CT		
Smith	John				8						M	
						1					H	
Cook	Jane				9						H	

FOR OFFICIAL USE ONLY — QUALIFICATIONS ACCORDING TO SUBPART M

Indicate the applicable regulatory citation under which the following individuals are qualified: Each laboratory director, technical consultant, technical supervisor, clinical consultant, general supervisor, cytology general supervisor, and those testing personnel and cytotechnologists sampled during the survey process.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0151. Expiration Date: XX/XX/XXXX. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

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