

**Genetics & Public Policy Center
Laboratory Director Survey**

Q1. Does your laboratory conduct genetic testing?

- a) Yes, clinical genetic testing only
- b) Yes, research genetic testing only
- c) Yes, both clinical and research genetic testing
- d) No, we refer all genetic testing out to other laboratories [END SURVEY]
- e) No, we do not perform any genetic testing [END SURVEY]

Q2. Does your laboratory ever report individual research results to providers or patients?

- a) Yes
- b) No [END SURVEY if Q1=b]

Q3. Does your laboratory conduct genetic testing ONLY for newborn screening?

- a) Yes [END SURVEY]
- b) No

Q4. Does your laboratory conduct genetic testing ONLY for infectious disease?

- a) Yes [END SURVEY]
- b) No

Q5. What kind of genetic testing does your laboratory conduct (choose as many as apply)?

- a) Molecular genetic testing
- b) Biochemical genetic testing
- c) Cytogenetic genetic testing

[TO CONTINUE, PARTICIPANTS HAD TO MEET ONE OF THE FOLLOWING QUALIFICATION PATHS:]

q1=a and q3=b and q4=b and Q5 does not equal c only

q1=b and q2=a and q3=b and q4=b and Q5 does not equal c only

q1=c and q3=b and q4=b and Q5 does not equal c only

Q6 was not used for this paper

Q7. Which of the following BEST describes your laboratory or parent institution?

- a) Commercial or independent
- b) University or Medical School (public or private)
- c) Other hospital (public or private)
- d) VA or military hospital
- e) Other

Q8. What is the highest degree you, the laboratory director, have received?

- a) MD or DO
- b) PhD
- c) MD and PhD
- d) MS or MA
- e) Other

Q9-Q12 not used in this report

[IF Q5=B THEN ASK]

Q13. Approximately how many clinical genetic test requisitions for BIOCHEMICAL genetic testing does your laboratory process per year? Please give your best estimate.

- a) Fewer than 250
- b) 250-999
- c) 1,000-4,999
- d) 5,000-9,999
- e) 10,000-14,999
- f) 15,000 or more

[IF Q5=A THEN ASK]

Q14. Approximately how many clinical genetic test requisitions for MOLECULAR genetic testing does your laboratory process per year? Please give your best estimate.

- a) Fewer than 250
- b) 250-999
- c) 1,000-4,999
- d) 5,000-9,999
- e) 10,000-14,999
- f) 15,000 or more

Q15. How many genetic tests are offered by your laboratory and are conducted in-house? Please count each test that has, or could have, it's own separate report. (Example: A 23-mutation panel for cystic fibrosis is one test. A thrombosis panel comprising DNA tests for factor V Leiden, prothrombin, and MTHFR counts as three tests.)

- a) Fewer than 5
- b) 5-19
- c) 20-49
- d) 50-99
- e) 100 or more

Q16-Q18 not used in this report

Q19. By which organizations is your laboratory accredited or licensed as a molecular or biochemical diagnostic laboratory? (choose all that apply)

- a) CLIA
- b) JCAHO (Joint Commission on Accreditation of Healthcare Organizations)
- c) CAP-LAP (College of American Pathologists Laboratory Accreditation Program)
- d) COLA (Commission on Office Laboratory Accreditation)
- e) NYS-CLEP (New York State Clinical Laboratory Evaluation Program)
- f) None of the above

[IF Q19=A THEN ASK]

Q20. Is your laboratory CLIA-certified for high-complexity testing?

- a) Yes
- b) No

[IF Q20=A THEN ASK]

Q21. For which specialties is your laboratory CLIA-certified?

- a) Histocompatibility
- b) Microbiology
- c) Diagnostic immunology
- d) Chemistry
- e) Hematology
- f) Immunohematology
- g) Pathology
- h) Radiobioassay
- i) Clinical cytogenetics

Q22-Q34 not used in this report

Q35. For what percentage of the genetic tests offered by your laboratory do you conduct some sort of proficiency testing?

- a) 0%
- b) 1-24%
- c) 25-49%
- d) 50-74%
- e) 75-99%
- f) 100%

Q36. Does your laboratory participate in a formal, external proficiency testing program?

- a) Yes, for all available formal, external proficiency testing programs
- b) Yes, for some formal, external proficiency testing programs
- c) No, because formal, external proficiency testing programs are not available for our tests
- d) No, we do not participate in formal, external proficiency testing programs

[IF Q36=B OR D THEN ASK]

Q37. Which of the following, if any, are reasons your laboratory does not participate in a formal, external proficiency testing programs (choose as many as apply)?

- a) None available
- b) Internal proficiency testing is adequate
- c) Formal, external proficiency testing is too expensive
- d) Formal, external proficiency testing does not provide timely feedback
- e) Other (please explain)

Q38. When a formal external proficiency-testing program is NOT available, does your laboratory perform proficiency testing using some other mechanism?

- a) Yes, for all tests
- b) Yes, for some tests
- c) No

[IF Q38=B OR C THEN ASK]

Q39. Which of the following, if any, are reasons your lab does not perform proficiency testing using some other mechanism when a formal program does not exist?

- a) We are the sole source for our test(s)
- b) Proficiency testing is not necessary for the types of tests we perform
- c) We use competency testing to document our laboratory proficiency
- d) Our test volume is too low to justify developing a proficiency testing program
- e) Other [fill in]

[IF Q36=A OR B THEN ASK]

Q40. How many times in the past two years has your laboratory been found to be deficient in any way on a formal external proficiency test?

Q41 not used in this report

Q42. Overall, in your opinion, how useful is proficiency testing for improving the quality of the genetic testing performed by the laboratory industry?

- a) Very useful
- b) Somewhat useful
- c) Not too useful
- d) Not useful at all

Q43-Q46 not used in this report

Q47. What types of errors have been detected in your laboratory during the past two years? (Choose all that apply).

- a) Referrer ordered incorrect test
- b) Referrer labeled specimen incorrectly
- c) Patient's transfusion was not reported by referrer
- d) Contamination of specimen before receipt by laboratory
- e) Sample switch at specimen receipt
- f) Transcription error at specimen receipt
- g) Sample switch during specimen testing
- h) Error in written protocol
- i) Faulty reagent
- j) Equipment failure
- k) Contamination of specimen during specimen testing
- l) Data transcription error
- m) Software error in data analysis
- n) Human error in data analysis
- o) Misinterpretation of data
- p) Typographical error on test report
- q) Wrong results reported to patient / provider
- r) Other [please describe]

[SHOW ONLY ANSWERS SELECTED IN Q47]

Q48. Which was the most frequent type of error over the past 2 years?

- a) Referrer's ordering incorrect genetic test

- b) Referrer labeled specimen incorrectly
- c) Patient's transfusion was not reported by referrer
- d) Contamination of specimen before receipt by laboratory
- e) Sample switch at specimen receipt
- f) Transcription error at specimen receipt
- g) Sample switch during specimen testing
- h) Error in written protocol
- i) Faulty reagent
- j) Equipment failure
- k) Contamination of specimen during specimen testing
- l) Data transcription error
- m) Software error in data analysis
- n) Human error in data analysis
- o) Misinterpretation of data
- p) Typographical error on test report
- q) Wrong results reported to patient/provider
- r) Other [fill in]

Q49. Give your best estimate of how many incorrect test reports were issued by your laboratory in the past 2 years?

Q50-Q55 not used in this report

Q56. Please indicate whether you agree or disagree with the following statements:

- a. CLIA should create a genetic testing specialty for molecular and biochemical genetic tests.**
 - a) Strongly agree
 - b) Agree
 - c) Disagree
 - d) Strongly disagree

Q56b-Q56i not used in this report

Q57-Q65 not used in this report