# Quality Control Log Instructions

**Purpose:** The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements for waived testing state that a testing site must follow the current manufacturer’s instructions provided with the test, including instructions for

quality control (QC).

QC is designed to detect problems arising from reagent or test kit deterioration, instrument malfunction, improper environmental conditions, or operator error. Performing QC testing procedures assures that the test performs as expected and alerts the user when problems occur. QC procedures should describe the type of controls to be used, how to perform QC testing, frequency of QC testing, and actions to be taken when QC results are unacceptable.

QC material should be treated the same as patient samples by being tested in the same way patient samples would be tested. QC is usually performed:

* With each new operator
* After an instrument is serviced
* When reagent or test kit lots are changed
* When reagent or test kit temperatures exceed the manufacturer’s acceptable temperature range
* After calibration
* When patient results seem questionable

Refer to the manufacturer’s instructions for specific QC requirements for each test your testing site performs. Each testing site should determine the appropriate QC frequency for each test system. Remember that the frequency of QC testing cannot be less than what is specified in the manufacturer’s instructions.

**Note: Qualitative tests** are interpreted as positive, negative; reactive, nonreactive; or invalid. **Quantitative tests** give a number result that corresponds to the amount of substance being measured, are reported in specific measurement units, and have an expected range.

# Results Log Instructions – Qualitative Test

1. Record the facility information and test name on the top of the form.
2. Enter the date of the test, sample number, patient name or ID, test results, lot number, and expiration date of test.
3. The person performing the test should initial the results after verifying that all the information has been entered correctly.

# Results Log Instructions – Quantitative Test

1. Record the facility information, test name, and reportable range for the test on the top of the form.
2. Enter the date of the test, sample number, patient name or ID, test results, lot number, and expiration date of test.
3. The person performing the test should initial the results after verifying that all the information has been entered correctly.

# Results Log with Quality Control (QC) Instructions – Qualitative Test

1. Record the facility information and test name on the top of the form.
2. Record the QC material lot number, expiration date, and positive and negative control results.
3. If the results are acceptable, QC passes. Patient results can be reported.
4. If the results are not acceptable, QC fails. Troubleshoot (check expiration dates, storage condition, etc.), retest the QC, and document the corrective action taken.

# Results Log with QC Instructions – Quantitative Test

1. Record the facility information, test name, and reportable range on the top of the form.
2. Record the QC material lot number, expiration date, and positive and negative control results.
3. If the results are acceptable, QC passes. Patient results can be reported.
4. If the results are not acceptable, QC fails. Troubleshoot (check expiration dates, storage condition, etc.), retest the QC, and document the corrective action taken.

# Results Log Instructions – Multiple Tests

1. Record the facility information on the top of the form.
2. Record the date, sample number, patient ID, test name, reportable range (if applicable), test result, lot number, expiration date, and initials of the individual performing the test.

**Contents**

There are many ways to record results. A blank results log is included, along with an example log demonstrating how to enter site-specific information.

1. Example of Results Log – Qualitative Test

2. Blank Results Log – Qualitative Test

3. Example of Results Log with QC – Qualitative Test

4. Blank Results Log with QC – Qualitative Test

5. Example of Results Log – Quantitative Test

6. Blank Results Log – Quantitative Test

7. Example of Results Log with QC – Quantitative Test

8. Blank Results Log with QC – Quantitative Test

9. Example of Results Log – Multiple Tests

10. Blank Results Log – Multiple Tests

|  |  |
| --- | --- |
| **Facility:** | **Dr. Smith’s Office** |
| **Location:** | **123 Main Street** |
|  | **Atlanta, GA 55555** |

|  |  |  |  |
| --- | --- | --- | --- |
| **Test name:** | **XYZ Strep antigen** |  |  |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Date | Sample  Number | Patient Name/ Patient ID | Test  Result | Test Lot  Number | Test  Exp. Date | Initials |
| **1** | **5/7/2024** | **5/5/2018** | **Donald Smith** | **NEG** | **Bd-0679** | **11/30/2024** | **CO** |
| **2** | **5/7/2024** | **5/5/2019** | **Chris White** | **POS** | **Bd-0679** | **11/30/2024** | **CO** |
| **3** | **5/8/2024** | **5/6/1930** | **Sam Jones** | **NEG** | **Bd-0679** | **11/30/2024** | **CO** |
| **4** |  |  |  |  |  |  |  |
| **5** |  |  |  |  |  |  |  |
| **6** |  |  |  |  |  |  |  |
| **7** |  |  |  |  |  |  |  |
| **8** |  |  |  |  |  |  |  |
| **9** |  |  |  |  |  |  |  |
| **10** |  |  |  |  |  |  |  |
| **11** |  |  |  |  |  |  |  |
| **12** |  |  |  |  |  |  |  |
| **13** |  |  |  |  |  |  |  |
| **14** |  |  |  |  |  |  |  |
| **15** |  |  |  |  |  |  |  |

Results Log – Qualitative Test – Example

\* Reportable range is the range of results for which a test system has proved to yield accurate results. This is usually found in the current manufacturer’s instructions for the test.

Results Log – Qualitative Test

|  |  |
| --- | --- |
| **Facility:** |  |
| **Location:** |  |
|  |  |

**Test Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | Date | Sample  Number | Patient Name/ Patient ID | Test  Result | Test Lot  Number | Test  Exp. Date | Initials |
| **1** |  |  |  |  |  |  |  |
| **2** |  |  |  |  |  |  |  |
| **3** |  |  |  |  |  |  |  |
| **4** |  |  |  |  |  |  |  |
| **5** |  |  |  |  |  |  |  |
| **6** |  |  |  |  |  |  |  |
| **7** |  |  |  |  |  |  |  |
| **8** |  |  |  |  |  |  |  |
| **9** |  |  |  |  |  |  |  |
| **10** |  |  |  |  |  |  |  |
| **11** |  |  |  |  |  |  |  |
| **12** |  |  |  |  |  |  |  |
| **13** |  |  |  |  |  |  |  |
| **14** |  |  |  |  |  |  |  |
| **15** |  |  |  |  |  |  |  |

*\* Reportable range is the range of results for which a test system has proved to yield accurate results. This is usually found in the current manufacturer’s instructions for the test.*

Results Log with QC – Qualitative Test – Example

|  |  |
| --- | --- |
| **Facility:** | **Dr. Smith’s Office** |
| **Location:** | **123 Main Street** |
|  | **Atlanta, GA 55555** |
|  |

|  |  |
| --- | --- |
| **Test name:** | **XYZ Strep antigen** |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Date** | **Sample ID/**  **Patient ID** | **Test Result** | **Initials** | **Test Lot No.** | **Test  Exp. Date** | **QC Lot/  Exp. Date** | **Positive Control Results** | **Negative Control Results** |
| **1** | **5/5/2024** | **5-05-20 / Tom Jones** | **NEG** | **SH** | **Bjz-3** | **8/31/24** | **108-OCB / 9-30-12** | **POS** | **NEG** |
| **2** | **5/6/2024** | **5-05-22 / Mattie Dunn** | **NEG** | **CO** | **Bjz-3** | **8/31/24** | **108-OCB / 9-30-12** | **POS** | **NEG** |
| **3** |  |  |  |  |  |  |  |  |  |
| **4** |  |  |  |  |  |  |  |  |  |
| **5** |  |  |  |  |  |  |  |  |  |
| **6** |  |  |  |  |  |  |  |  |  |
| **7** |  |  |  |  |  |  |  |  |  |
| **8** |  |  |  |  |  |  |  |  |  |
| **9** |  |  |  |  |  |  |  |  |  |
| **10** |  |  |  |  |  |  |  |  |  |
| **11** |  |  |  |  |  |  |  |  |  |
| **12** |  |  |  |  |  |  |  |  |  |

\* Reportable range is the range of results for which a test system has proved to yield accurate results. This is usually found in the current manufacturer’s instructions for the test.

Results Log with QC – Qualitative Test

|  |  |
| --- | --- |
| **Facility:** |  |
| **Location:** |  |
|  |  |

**Test Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Date** | **Sample ID/**  **Patient ID** | **Test Result** | **Initials** | **Test Lot No.** | **Test  Exp. Date** | **QC Lot/  Exp. Date** | **Positive Control Results** | **Negative Control Results** |
| **1** |  |  |  |  |  |  |  |  |  |
| **2** |  |  |  |  |  |  |  |  |  |
| **3** |  |  |  |  |  |  |  |  |  |
| **4** |  |  |  |  |  |  |  |  |  |
| **5** |  |  |  |  |  |  |  |  |  |
| **6** |  |  |  |  |  |  |  |  |  |
| **7** |  |  |  |  |  |  |  |  |  |
| **8** |  |  |  |  |  |  |  |  |  |
| **9** |  |  |  |  |  |  |  |  |  |
| **10** |  |  |  |  |  |  |  |  |  |
| **11** |  |  |  |  |  |  |  |  |  |
| **12** |  |  |  |  |  |  |  |  |  |

\* Reportable range is the range of results for which a test system has proved to yield accurate results. This is usually found in the current manufacturer’s instructions for the test.

Results Log – Quantitative Test – Example

|  |  |
| --- | --- |
| **Facility:** | **Dr. Smith’s Office** |
| **Location:** | **123 Main Street** |
|  | **Atlanta, GA 55555** |

**Test Name: XYZ Strep antigen Reportable Range: 5-400 U/L**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Date** | **Sample  Number** | **Patient Name/ Patient ID** | **Test Result** | **Test Lot  Number** | **Test  Exp. Date** | **Initials** |
| 1 | **5/5/2024** | **05052018** | **Steve Smith** | **Male: 30 U/L** | **Bd-0679** | **11/30/2025** | **CO** |
| 2 | **5/6/2024** | **05052019** | **Chris White** | **Male: 22 U/L** | **Bd-0679** | **11/30/2025** | **CO** |
| 3 | **5/7/2024** | **05061930** | **Sam Jones** | **Female: 14 U/L** | **Bd-0679** | **11/30/2025** | **CO** |
| 4 |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |  |
| 7 |  |  |  |  |  |  |  |
| 8 |  |  |  |  |  |  |  |
| 9 |  |  |  |  |  |  |  |
| 10 |  |  |  |  |  |  |  |

*\* Reportable range is the range of results for which a test system has proved to yield accurate results. This is usually found  
in the current manufacturer’s instructions for the test.*

Results Log – Quantitative Test

|  |  |
| --- | --- |
| **Facility:** |  |
| **Location:** |  |
|  |  |

**Test Name: Reportable Range:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Date** | **Sample  Number** | **Patient Name/ Patient ID** | **Test Result** | **Test Lot  Number** | **Test  Exp. Date** | **Initials** |
| 1 |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |  |
| 7 |  |  |  |  |  |  |  |
| 8 |  |  |  |  |  |  |  |
| 9 |  |  |  |  |  |  |  |
| 10 |  |  |  |  |  |  |  |

*\* Reportable range is the range of results for which a test system has proved to yield accurate results. This is usually found  
in the current manufacturer’s instructions for the test.*

Results Log with QC – Quantitative Test – Example

|  |  |
| --- | --- |
| **Facility:** | **Dr. Smith’s Office** |
| **Location:** | **123 Main Street** |
|  | **Atlanta, GA 55555** |

|  |  |
| --- | --- |
| **Test name:** | **XYZ Strep antigen** |

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Date** | **Sample ID/  Patient ID** | **Test Results** | **Initials** | **Test Lot number/  Test Exp. Date** | **QC Level 1  Control** | **QC Level 2  Control** |
| **1** | **5/5/2024** | **5/5/2018 / Steve Smith** | **Male: 30U/L** | **CO** | **C843 / 06/30/2025** | Lot #: **91750566** | Lot #: **91750566** |
| Range: **43-78 U/L** | Range: **132-242 U/L** |
| Result: **57 U/L** | Result: **203 U/L** |
| **2** | **5/6/2024** | **5/05/2019 / Chris White** | **Male: 22U/L** | **CO** | **C843 / 06/30/2025** | Lot #: **91750566** | Lot #: **91750566** |
| Range: **43-78 U/L** | Range: **132-242 U/L** |
| Result: **58 U/L** | Result: **221 U/L** |
| **3** | **5/7/2024** | **5/05/1930 / Sam Jones** | **Female: 14U/L** | **CO** | **C843 / 06/30/2025** | Lot #: **91750566** | Lot #: **91750566** |
| Range: **43-78 U/L** | Range: **132-242 U/L** |
| Result: **57 U/L** | Result: **221 U/L** |
| **4** |  |  |  |  |  | Lot #: | Lot #: |
| Range: | Range: |
| Result: | Result: |
| **5** |  |  |  |  |  | Lot #: | Lot #: |
| Range: | Range: |
| Result: | Result: |
| **6** |  |  |  |  |  | Lot #: | Lot #: |
| Range: | Range: |
| Result: | Result: |
| **7** |  |  |  |  |  | Lot #: | Lot #: |
| Range: | Range: |
| Result: | Result: |
| **8** |  |  |  |  |  | Lot #: | Lot #: |
| Range: | Range: |
| Result: | Result: |
| Result: | Result: |

\* Reportable range is the range of results for which a test system has proved to yield accurate results. This is usually found in the current manufacturer’s instructions for the test.

Results Log with QC – Quantitative Test

|  |  |
| --- | --- |
| **Facility:** |  |
| **Location:** |  |
|  |  |

|  |  |
| --- | --- |
| **Test name:** |  |

\* Reportable range is the range of results for which a test system has proved to yield accurate results. This is usually found in the current manufacturer’s instructions for the test.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Date** | **Sample ID/  Patient ID** | **Test Results** | **Initials** | **Test Lot number/  Test Exp. Date** | **QC Level 1  Control** | **QC Level 2  Control** |
| **1** |  |  |  |  |  | Lot #: | Lot #: |
| Range: | Range: |
| Result: | Result: |
| **2** |  |  |  |  |  | Lot #: | Lot #: |
| Range: | Range: |
| Result: | Result: |
| **3** |  |  |  |  |  | Lot #: | Lot #: |
| Range: | Range: |
| Result: | Result: |
| **4** |  |  |  |  |  | Lot #: | Lot #: |
| Range: | Range: |
| Result: | Result: |
| **5** |  |  |  |  |  | Lot #: | Lot #: |
| Range: | Range: |
| Result: | Result: |
| **6** |  |  |  |  |  | Lot #: | Lot #: |
| Range: | Range: |
| Result: | Result: |
| **7** |  |  |  |  |  | Lot #: | Lot #: |
| Range: | Range: |
| Result: | Result: |
| **8** |  |  |  |  |  | Lot #: | Lot #: |
| Range: | Range: |
| Result: | Result: |
| Result: | Result: |

Results Log – Multiple Tests – Example

|  |  |
| --- | --- |
| **Facility:** |  |
| **Location:** |  |
|  |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Date** | **Sample  Number** | **Patient Name/ Patient ID** | **Test Name** | **\*Reportable Range** | **Test  Result** | **Test  Lot No./ Exp. Date** | **Initials** |
| 1 | ***5/5/2024*** | ***05052018*** | ***Donald Smith*** | ***XYZ Strep*** | ***N/A*** | ***NEG*** | **Bd-0679 / 11/30/2025** | **CO** |
| 2 | ***5/5/2024*** | ***05052019*** | ***Chris White*** | ***XYZ Strep*** | ***N/A*** | ***POS*** | **Bd-0680 / 11/30/2025** | **CO** |
| 3 | ***5/5/2024*** | ***05052020*** | ***Tom Jones*** | ***Occult blood – 123*** | ***N/A*** | ***NEG*** | **Bjz-3 / 8/31/2025** | **CO** |
| 4 | ***5/5/2024*** | ***05052021*** | ***Pam Roberts*** | ***Urine HCG-ABC*** | ***N/A*** | ***NEG*** | **Trp-23 / 11/30/2025** | **CO** |
| 5 | ***5/5/2024*** | ***05052022*** | ***Mattie Dunn*** | ***Occult blood - 123*** | ***N/A*** | ***NEG*** | **Bjz-3 / 8/31/2025** | **CO** |
| 6 | ***5/5/2024*** | ***05052023*** | ***Steve Smith*** | ***XYZ ALT*** | ***5-400 U/L*** | ***Male: 33 U/L*** | **C843 / 6/30/2025** | **CO** |
| 7 |  |  |  |  |  |  |  |  |
| 8 |  |  |  |  |  |  |  |  |
| 9 |  |  |  |  |  |  |  |  |
| 10 |  |  |  |  |  |  |  |  |

\* Reportable range is the range of results for which a test system has proved to yield accurate results. This is usually found in the current manufacturer’s instructions for the test.

Results Log – Multiple Tests

|  |  |
| --- | --- |
| **Facility:** |  |
| **Location:** |  |
|  |  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Date** | **Sample  Number** | **Patient Name/ Patient ID** | **Test Name** | **\*Reportable Range** | **Test  Result** | **Test  Lot No./ Exp. Date** | **Initials** |
| 1 |  |  |  |  |  |  |  |  |
| 2 |  |  |  |  |  |  |  |  |
| 3 |  |  |  |  |  |  |  |  |
| 4 |  |  |  |  |  |  |  |  |
| 5 |  |  |  |  |  |  |  |  |
| 6 |  |  |  |  |  |  |  |  |
| 7 |  |  |  |  |  |  |  |  |
| 8 |  |  |  |  |  |  |  |  |
| 9 |  |  |  |  |  |  |  |  |
| 10 |  |  |  |  |  |  |  |  |

\* Reportable range is the range of results for which a test system has proved to yield accurate results. This is usually found in the current manufacturer’s instructions for the test.