

Repeat Testing For Newborn Specimens

Tracking Number: CN004
Version 4.4

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I. Title

Repeat Testing for Newborn Specimens

II. Principle

Results which were scored “red”, prevented from release, must be retested. Retesting requires repunching the specimen, must minimize rendering the specimen inadequate, and must be done on a timely basis.

III. Specimen Collection and Type

Refer to the newborn screening assay protocols.

IV. Equipment and Supplies

Refer to the TRA/BIO, TSH/N17OHP, IRT assay protocols.

V. Reagents

Refer to the TRA/BIO, TSH/ N17OHP, and IRT assay protocols.

VI. Calibration and Quality Control

Refer to the TRA/BIO, TSH/17OHP, and IRT assay protocols.

VII. Procedures**A. Rules Used for Repeat Testing**

Unless a specimen is on the Repeat List, the specimen cannot be punched using Specimen Gate.

1. If a run or tray is prevented from release, repeat the testing for the run or tray for the single analyte.
2. If a result for a single specimen is prevented from release on a tray that was released and the specimen is not inadequate, include it with the day's new specimens and repeat testing for all prevented analytes. Reasons to repeat the testing for a single specimen may include:
 - a. A result for TRA/BIO is from an unresolved peak. An unresolved peak for TRA that has a result that is **less than or equal to 50 must be repeated on the same day.**
 - b. A result for 17OHP, TSH or IRT is >STD.

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- c. A result for 17OHP, TSH, or IRT is <STD. A TRA/BIO result <STD may or may not need retesting. See Supervisor's Review and Release Protocol.
- d. Results from two specimens with the same barcode.
 - 1) Retrieve the collection card and TRF for both specimens.
 - 2) Match the collection card to the TRF using form number, name, birthdate, and collection date.
 - 3) Label the collection card and TRF with a new barcode accession numbers for both specimens.
 - 4) Reenter the TRF using the new accession numbers.
 - 5) Call GDB to have the original TRFs deleted from the system.
- e. A result for TRA when TRB is >25.
- f. A result judged invalid due to laboratory error or by GDLB.

NOTE: If an acceptable blood spot is not available for repeat testing, the specimen is treated as an inadequate. The Supervisor must ensure that the Area Genetic Center is notified so that appropriate action will be taken to obtain a new specimen.

B. Repeat List

- 1. Print the repeat list each morning before your laboratory begins testing the day's new specimens. All newborn screening results which were prevented by your laboratory and GDLB QA are listed and must be tested the day it is printed.
- 2. To print the repeat list, refer to the NBS Supervisor's Daily R&R Using Specimen Gate protocol.

Specimens on the repeats list will be tracked on the Supervisor's PC. If on repeat testing, the result is released by the supervisor, the specimen drops off the repeats list. If prevented or not tested, the specimen stays on the list.

C. Setting up the Run When There Are Repeats

- 1. To repeat a complete run or tray for a single analyte or a combination of Hgb with TRA and/or BIO, set up the tray or run as a separate run.
- 2. To repeat an individual specimen, e.g., specimen with a 17OHP, TSH, or IRT result <STD or a 17OHP, TSH, or IRT result >STD, include the

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individual specimen with the day's new specimens and follow protocol for testing.

3. To repeat an individual specimen which was prevented due to an unresolved TRA or BIO peak,
 - a. Punch W6, blank filter paper, before and after each specimen repeated because of an unresolved peak.
 - b. After analysis, score the resolved peak "green" and report the result as per protocol, if it is acceptable.
4. To repeat a run or a tray for Hgb only,
 - a. Resample the microtiter plate, if possible.
5. To repeat a run or a tray for TSH, 17OHP, or IRT only,
 - a. Combine specimens for repeat testing with the day's new specimens or set up as a separate run.
 - b. Run a maximum of 4 trays per calibration curve. [Physically the AutoDELFIA can run up to twelve trays. To run twelve trays, set up three work lists (use three sets of standards for the three calibration curves) of four plates each.

VIII. Calculations

NA

IX. Reporting Results

Refer to the TRA/BIO, TSH/17OHP, and IRT assay protocols.

X. Procedure Notes

NA

XI. Limitations of Procedure

NA

XII. References

Refer to the TRA/BIO, TSH/17OHP, and IRT assay protocols.