

**Newborn Screening
Supervisor's Daily Review and Release
Using Specimen Gate**

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I. Title

Newborn Screening Supervisor's Daily Review and Release

II. Principle

At the completion of each day's testing, the supervisor at the screening laboratory must review and release the day's data. NAPS supervisor and any qualified CLS who is trained and authorized by the NAPS supervisor are allow to review and release results. Data files from the API300 and AutoDELFI A are downloaded to the Supervisor's PC. The data files are put through Specimen Gate, the QC software, to calculate results and score based on control rules for determination of run/tray/result status. Software provides QC plots, trend plots, calibration curves, specimen's testing history, repeat list and presumptive positive list.

Security is maintained with different access levels to the data base. Staff with security level for **read only** can view the run data using the procedures below but cannot make any changes to the data. Higher levels of access are allowed additional functions.

III. Specimen and Collection Type

Refer to the newborn screening protocols.

IV. Equipment and Supplies

Refer to the newborn screening protocols.

V. Reagents

Refer to the newborn screening protocols.

VI. Calibration and Quality Control

Refer to the newborn screening protocols.

VII. Procedures

A. Review and Release

1. Access to Supervisor's PC
 - a. Use Ctrl/Alt/Delete to login.
 - b. Enter user name and password. This opens to the GDLB-PNS and NBS Program Menu. Supervisors performing review and release must log on at Level 2.
 - c. Click **Routine Program/Result Viewer**.
NOTE: Click **Result Viewer (Training Mode)** to review and release training runs. Additionally, for GDLB only, click **Result Viewer (QC Mode)** for kit evaluation runs.
2. Review Information on Checklist for Accuracy

Verify that the entries, e.g., run #, test date, instrument ID, julian date, etc, are correct on the checklist. If there is an error or omission, correct the entry. Fax the completed checklist to GDLB by 9:00 AM each morning.

3. Select a Run

- a. Click **Work Flow/NAPS Review** on the left of the **Specimen Gate Result Viewer** main menu screen. This takes you to a list of runs available for review and release. Other icons on the **Work Flow** list include

Punched - lists the specimens that have been punched at the DBS puncher workstation and is in the database but a worklist has not yet been created for analysis with system ID

At Worklist – worklist is created, waiting for results

Measured – normally should be empty, if accession numbers are listed, they are stuck somewhere in the system, call Proxy

QA Review – runs ready to go to or at GDLB QA

QA Release – runs reviewed by GDLB QA

QA Released – results released to SIS

NOTE: With Specimen Gate, your laboratory can track the status of your runs from punching to the release of results to SIS by GDLB QA.

- b. Sort the list of runs by

Assay – **All** for all assays or a single assay, AAAC, APSC, IRT, 17OHP, or TSH. In the main use **All**.

Instrument – **All** for all instruments or a single instrument. In the main use **All**.

Date – all current assay or by assays by specific test dates

List max length – ignore, for GDLB QA only

- c. View run information. Information for the run includes

ID - ID number assigned by the system that you would not be using

Assay

Kitlot

Batch ID – contains the run number, format, for example, is yymmdd01 for Run 1

Date Started – this is test date

Instrument

Plates – this is number of plates in the run

Samples – this is number of total samples in the run including Stds and QC

Run Status – status is OK for release, held or notify, or prevented

User- ignore, for GDLB QA

NOTE: If there is a run on the checklist that is not on the PC screen, call Proxy.

4. Review Calibration Curve

- a. Double click on a run or highlight a run and click **Open** to open a run for review and release. If the run is an AutoDELFIA run, proceed to b. below. If the run is an APSC (Astoria Pacific Spot Check) run on the API300, you

must make the following selection:

- 1) Use the drop down menu in **Groups** to select **Transferase** to review a transferase run and **Biotinidase** to review a biotinidase run. This selection must be made to score transferase and biotinidase results independently.
 - 2) Use the drop down menu in **Analytes** to select **TRA** to view the transferase calibration curve and data.
 - 3) Use the drop down menu in **Analytes** to select **BIO** to view the biotinidase calibration curve and data.
- b. Click **Calibration**.
- 1) View the calibration curve. It is a spline smooth curve. There are two curves on the screen, one is the calibration curve, the curve for the run, and other is the reference curve, the curve for the run before the current run. The x axis is concentration for immunoassays or activity for enzyme assays and the y axis is counts for sandwich or % binding for competitive immunoassays or volts for enzyme assays.
 - 2) View data for the calibration curve, **Slope, Intercept, ED20, ED50, and ED80**.
 - 3) To identify the curve, move the cursor to a curve and the curve name is shown on the screen, Calibration curve or Reference curve, with test date, yymmdd, system ID, run ID, X and Y coordinates.
 - 4) Click **Points** to see a tabular presentation of the data points for the calibration curve. Standards are name by concentration and not as Std A, B, C, D, E, or F. The counts or volts for each replicate is shown under **Replicate point, Resp =**, and each replicate is checked or unchecked in the **Is active** column. A replicate that is checked means the point was used to construct the standard curve. A replicate that is unchecked means the point is an outlier and was not used to construct the standard curve. Data are available for both the calibration and reference curve. Click **Close**.
5. Re-evaluate Calibration Data to Edit/Swap the STDs or Swap SQCs
- a. Delete a point. SG does not have an outlier function and SG constructs the best curve that fits all data points. SG does have a re-evaluate function where an outlier point can be deleted and a new standard curve constructed. When a standard is deleted, a **Rejected** flag in the **Flag** column is shown in **Results/Grid** and is scored **red**. Use this function sparingly and only to delete one replicate as an outlier, e.g., one replicate of Std A, >1000 counts.
 - 1) Click **Calibration/Points**.
 - 2) Remove the \surd from the box for the standard to be deleted in the **Is active** column.

- 3) Click **Close** to view the edited curve.
- 4) Click **Results/Grid** to view the changes in results, click **OK** when the prompt appears on the screen:

Calibration has changed and recalculation is needed.
Click OK to recalculate now.
- 5) Select the radio button **Full calculation** for the current kit lot when ask:

What kind of calculation do you want to perform?

Do not select **Result code calculation only**.
- 6) Click **Save**.
- 7) Reverse the process by adding the \surd back to the box of the deleted standard.
- b. Swap standards or SQCs when you have physically confirmed that standards or SQCs were place onto the AutoDELFIA in the wrong order.
 - 1) Click **Result/Grid**.
 - 2) Select the 2 standards or SQC you want to swap. Highlight the first, hold down **Ctrl**, highlight the second, e.g., select Std B, Ctrl, select Std C.
 - 3) Right click to select **Swap Sample definitions**. This opens the **Open Change Sample Type** screen. On the screen are the two selected standards.

Std B ↔ Std C.
 - 4) Enter comment into **Enter reason for operation**. A comment must be enter in order to proceed.
 - 5) Click **OK**.
 - 6) Review the run with the edited standards or SQCs.
6. Review QC Data for an AutoDELFIA Run
 - a. Click **QC**, then LJ Plot (Levy Jennings).
 - 1) View the information on the screen. There is a LJ Plot for the following parameters:

CH – high system control
CL – low system control
CM – medium system control
CT – tray control
Median of initial – assay median
Plate median
ED20, ED50, and ED80
Intercept
Slope
STD A, (Total count for 17OHP, Blank for TSH/IRT), B, C, D, E, and F
Each plot shows concentration on the left side of the y axis and target

with 2SD and 3SD limits on the right side of the y axis. The x axis is test date. Data points within the red lines are points for the current run. Place the cursor on a data point to read the concentration and drag down away from the point to see the Run ID. You can view all data points from your laboratory or by specific instrument by using the drop down menu for **Instrument**.

- 2) Highlight a parameter. The parameter has a blue line around it. View additional information for the parameter in **All Points**, **Selected points**, and **Plotting Limits**. **All Points** show **Count**, total number of data points with the same lot number, and **Mean**, **SD**, and **CV** for the data plotted. **Selected points** show the same for a selected subset. To select the subset, put the cursor on the right of the first data point and drag to include the last data point, e.g., first test date for a new lot. **Plotting Limits** show **Target**, **SD Limit**, and **CV%**, GDLB defined mean, SD, and %CV. Click **Reset** to return original screen.
- b. Click **QC Summary** to view data points for each parameter for the current run only. If summary does not appear, click **Calculate** to have the software instruct SG to calculate the run as if it is an original run. Information on the screen include
 - Level** – identifies the parameter
 - Target** – set by GDLB for each parameter
 - 2 SD Range**
 - Point** – number of data points for the current lot
 - Frame** – is plate number
 - Value**
 - Z-Score** – SD from target
 - or + - a green or red bar, red if >3SD, for -SD or +SD from target
 - Flags** – SG, instrument flags
 - Notes** – space to enter comment
- c. Click **Grid** for a tabular presentation of the data for all parameters. Information on the screen include
 - Trace** – name of parameter
 - Date** – test date
 - Instrument** – identifies the instrument used
 - Run ID** – system assigned Run ID, is not run number
 - Target**
 - 2 SD Range**
 - Point** - number of data points for the current lot
 - Value**

Z-Score

- or + - a green or red bar for -SD or +SD from target

Notes – shows INACTIVE if deleted

- d. Click **Filter** to define what you to view. Select dates for the runs you want to view and select the radio button for number of points or number of runs. If number of points or runs selected is fewer than what is available from the dates selected, the most recent data are plotted .

7. Review QC Data for an APSC Run

All the keystrokes and information are basically the same as for an AutoDELFIA Run. However, an APSC run contains two assays, TRA and BIO. Therefore, you must select from **Groups** either the **Transferase** or **Biotinidase** QC data you wish to review. When **Biotinidase** is selected, select **BIO** from **Analytes**. When **Transferase** is selected, you can select **TRA**, **TRB**, **TRA-TRB**, or **Analytes** from **Analytes**. If you select **Transferase/Analytes**, you must use the drop down menu for **Plot** to select the parameter you wish to view. You cannot see all parameters at one time. Selections define the QC data you have for review for in all three modes, TRA, TRB, and TRA-TRB. If Analytes is not selected, to review standard curve parameters, i.e., Std A – E volts, slope, intercept, ED20 – ED80, select **Transferase/TRA**. To review SQC, select Transferase/TRA. SQC results in TRA determine if the run is in or out of control. To review TQC, assay median, and tray median select **Tranferase/TRA-TRB**. TQC results in TRA-TRB determine if the tray is in or out of control.

8. Review the Run

NOTE: SG does not provide a comment for 17OHP runs regarding whether all birth weights are imported, some BWs imported, or no BWs imported.

- a. Click **Results**. Screen defaults to **Results/Plate**.

For an APSC run, screen defaults to **Groups/Analytes**. This selection gives information for BIO, TRB, TRA, and TRA-TRB and allows you to review and score the biotinidase and the transferase assays simultaneously and identically which is not what you want. Narrow the selection to the biotinidase assay only or the transferase assay only. For transferase only, select **Transferase/Analytes**. For biotinidase only, select **Biotinidase/BIO**. Once a selection is made, you may need to click on a well with a result to refresh the screen for the correct SG scores.

See **Flag/Details** for the flags for the run/tray/result. **Analyte** lists the assay for which the flag was generated.

Information on the screen includes

- 1) Plate Map. Any well that has a flag and/or comment for that well has an “X” displayed in the well. Use the drop down menu for **Well Colors** to select how you want to view the wells.
 - a) **Sample role** – view as type of samples, yellow for standards, red for system or tray control, red for water cups, green for patients pink for proficiency test samples, and orange for reference samples.
 - b) **Severity** – green as released, yellow as held, or red as prevented
 - c) **Determination** – status is green for negatives, orange for 17OHP indeterminate, and blue for presumptive positive.
- 2) Assay information include Specimen Gate (SG) **Score, Test, (Test) Date, Instrument, Kit Lot, and Status, NAPS Review, Flag, flags for the run, and Details**, for comments for the run.

NOTE: In the Results/Plate screen, SG scores are by hierarchy, i.e., if the run is red, all trays and all results are red regardless of TQC results or individual flags for the result. View information in **Flag/Details** for the tray/result to determine status if scored using rules for trays/results.
- 3) Plate information include **SG Score, Flag, flags for the tray, Details**, comments for the tray, **Analyte, Source**, identifies the source of the flags and comments, and **Date**, identifies the date and time the flag/comment was created.
- 4) Well information include **Accession number, SG Score, Sample** (type), **Concentration, Phase**, e.g., is initial, **Determination**, e.g., positive I-P, **Flag, flags for the result, and Details**, for comments for a result.
- b. Click **Grid** to view the run in worksheet format. In general, select **<no filter>** for **Result filter** to see the entire run. Other choices are **Abnormal Patients, All Flagged Results, Calibrators, Controls, Flagged Calibrators, Flagged Controls, Patients Excluded** to see specific types of samples.
 - 1) View the information on the screen for an AutoDELFIA worksheet.

Plate – this identifies the elevator shelf used for incubation

LineNr – starts with 1 for well A01 for tray 1

Well (number)

Code Str – is accession number, calibrator, or control

Role – identifies the sample as calibrator, proficiency, patient, etc.

Counts

% Binding – for competitive immunoassay only

Flag – SG flags, instrument flags, and/or comments

Conc

Weight – for 17OHP only

Rpt count – counts the number of repeats, 1st repeat is Rpt=1, every time

a barcode is scanned into the system, it is counted. For example, if a specimen was scanned, punched, but the run was aborted, the next time this specimen is scanned and punched, Rpt=1

% Difference with previous – SG calculates % difference between the current and previous result

Result Code - is N/A for calibrator, control, and reference results, is I-P for presumptive positives and highlighted in blue, is I-IND for 17OHP indeterminates and highlighted in orange, and is I-N for initial negatives. Proficiency test results are coded NA.

Result Status – OK for green, is held or notify for yellow, or is prevented for red, the score is based on the flag for the result

NOTE: If a result is **held**, the reviewer must make a change to complete review and release. If you want additional review at GDLB's QA, keep it yellow and change it to **Notify**. Notify does not require a change.

2) View the information on the **Grid** screen for an APSC run with appropriate selections from **Groups** and **Analytes** (as with QC data review).

a) Select **Transferase/Analytes** for a transferase run

NOTE: If the selection is TRB, TRA, or TRA-TRB and not Analytes, you see only a partial picture, flags for the specific channel only, e.g., user modified in TRA only or incorrect SQC, close to zero, results in TRA-TRB.

Plate – this identifies the elevator shelf used for incubation

LineNr – starts with 1 for well A01 for tray 1

Well (number)

Code Str – is accession number

Role – identifies the sample as calibrator, proficiency, patient, etc.

TRB Volts – detector reading

TRB RFU

TRB Flags – flags for the blank channel, e.g., NP-no peak found or TrB>12

TRA Volts

TRA RFU

TRA Flags – flags for the active channel, e.g., UM-User modified or NP-no peak found

TRA-TRB RFU – calculated activity in active channel minus

calculated activity in blank channel, result that is released to SIS

TRA-TRB Result Code – I-P for positive, I-N for negative

TRA-TRB flags – flags for result (that is released to SIS)

- b) Select Biotinidase/BIO for a biotinidase run

Plate – this identifies the elevator shelf used for incubation

LineNr – starts with 1 for well A01 for tray 1

Well (number)

Code Str – is accession number

Role – identifies the sample as calibrator, proficiency, patient, etc.

BIO Volts

BIO ERU

BIO Result Code – I-P for positive, I-N for negative

BIO Flags

- c. To review chart tracing, highlight the first standard, (this is Std B, quirk in the software and it does not respond if you click Std A), right click to select **View API Peak Trace**. This takes you to the FASPac chart tracings. If you want to view a specific peak, highlight the specific result and right click **View API Peak Trace** and FASPac takes you to the specific peak for TRA, TRB, and BIO. All definitions for a red maker, yellow marker, resolved peaks, baseline, etc. remain the same.

9. Determine Run Status

- a. Use the following rules to score a run.
- 1) Score the run **red** if any one of any pair of system controls for TSH, 17OHP, or IRT is $> \pm 3SD$.
 - 2) Score the run **red** if one of the three system controls is $> \pm 3SD$ for TRA or BIO.
 - 3) Score the run **red** if two of any pair of system controls for TSH, 17OHP, or IRT is $> \pm 2SD$ but within $\pm 3SD$.
 - 4) Score the run **red** if any pair of system controls fails the R4s rule for TSH, 17OHP, or IRT.
 - 5) Score the run **green** if one of any pair of system controls for TSH, 17OHP, or IRT is $> \pm 2SD$ but within $\pm 3SD$. Specimen Gate scores the run **yellow** as a warning. If your laboratory considers this run acceptable score it **green**. If it is questionable, score it **yellow** for further review by GDLB QA or score it **red** if it is not acceptable.
 - 6) Score the run **green** if one or two of three system controls for TRA or BIO is $> \pm 2SD$ but within $\pm 3SD$. SG scores this run **yellow** as a warning. If your laboratory considers this run acceptable score it **green**. If it is questionable, score it **yellow** for further review by GDLB QA or score it **red** if it is not acceptable.
 - 7) Score the run **red** if all three system controls for TRA or BIO are

> $\pm 2SD$ but within $\pm 3SD$. SG scores this run yellow.

- 8) Score the run **green** if all system control results are within the $\pm 2SD$ limits and it is otherwise acceptable.
- 9) Review the **assay median**. If the assay median is outside the acceptable range, SG scores the run **yellow**.
Score the run **green** unless there is reason to keep it **yellow** or change it to **red**. (Use the tray median to score each tray.)
- 10) Score the run **green** if the standard curve has an outlier and the shape of the standard curve is consistent with prior curves. SG scores the run **yellow**.
- 11) Score a TSH run **red** if both replicates for Standard A have a flag for high count, exceeding limits set by GDLB. Flag for Plate view is **2 Std A > 1000** and flag in Grid view both Std A is **Revoked by**. SG does not treat Standard A as an outlier as with all other standards. Standard A is the blank and effects construction of the standard curve.

NOTE: If one replicate of Standard A has a flag for a high count, flag in Plate view is 1 Std A > 1000 and flag in Grid view is Revoked by, delete that replicate and re-evaluate to construct a new standard curve. See Section VII.A.5.

- 12) Swap standards to construct a new standard curve after you verified physically that the standards were placed on the AutoDELFIA in the wrong order. Score the run according to all current QC rules.
 - 13) Score a TSH, 17OHP, and/or IRT run **red** if during shutdown the AutoDelfia fails the washer probe performance check. Usually this occurs because a washer probe has become blocked and fails to wash the wells correctly during the run.
 - 14) Score the run **yellow** if for any reason you want additional review by GDLB's QA system.
- b. Score a run in the **Plate** screen. A run is scored green for released, yellow for notify (same as Held in MultiCalc), and red for prevented.

If you agree with the SG score for the run, tray, or results, you do not have to score. Simply keep the SG score. GDL QA can view the Assay Log to know who from your laboratory reviewed and released the run.

To score transferase runs/trays/results you **MUST** select **Transferase/Analytes** and entry for **Apply to** is **Selected analyte group: transferase**. To score biotinidase runs/trays/results you **MUST** select **Biotinidase/BIO** and entry for **Apply to** is **Selected analyte: apBTD** or **Selected analyte group: biotinidase**.

To score a run in the **Plate** screen

- 1) Click ... on the assay line.
- 2) View the **Add Flag** screen. Entry for **Apply to** defaults to the selected assay.

- 3) Select **Free Text**, **QC-OK**, or a **Fixed Comment** from the drop down menu for **Flag Type**.

If all you want to do is scored the run **green**, click **QC-OK**.

If you want to enter a fixed comment, select the comment and score as in 4) below. You will see the fixed comment in **Flag** and **Details** in **Results/Plate**.

Otherwise, select **Free Text**.

- 4) Select from the following from the **Severity** drop down menu:
- a) Info – if you want to add a comment only
 - b) Green OK - run is released
 - c) Yellow Notify – run is held, same as **Held** in MultiCalc
 - d) Yellow Held - requires an action to complete review and release, can change it to yellow, Notify, for further review by GDLB QA.
 - e) Red Prevented - run is prevented and must be repeated, if run is prevented, all trays and results change to **red**
 - f) Black Deleted
- 5) Enter a free text comment for the run in the **Comment** box if needed. Once a comment is entered, fixed or free, it cannot be changed or deleted. If the comment is incorrect or needs editing, write words to that effect and enter a new comment. All comments and flags are retained in the order created with the newest on top of the list.

NOTE: Specimen Gate allows you to score a run/tray/result from the **Plate** or **Grid** view regardless of what you are viewing in **Result**. Right click on a well in the **Plate** view or highlight a result in the **Grid** view. Select **Add Comment**. This opens the **Add Comment** window. Select for **Comment Type** a radio button for **Assay**, **Tray**, or **Sample**. If **Tray** is selected, the tray scored is the tray of the well or result line that was selected and tray number is displayed on the right. If **Sample** is selected, it is the well or result that was selected and the accession number is displayed on the right. Use the drop down menu for **Severity** and select **OK**, **Held**, or **Prevented**. Click OK.

Do not use the **Add Comment** feature to score an APSC run. When **Add Comment** is used, the assay is scored and therefore both the transferase and biotinidase analytes are scored the same. It is best to score the run/tray using the **Plate** view rather than the **Grid** view.

- c. Close the run at any time during review by clicking the X in upper right corner. Click **Save** to save all changes made and begin where you left off or **Discard** to start over the review of the run.

10. Determine Tray Status

- a. Use the following rules to score a tray.
- 1) Score the tray **red** if the PQC for TRA or BIO exceeds the limit set by GDLB. “PQC+3SD” appears as a flag for the tray.
 - 2) Score the tray **yellow** if any water cup on the tray exceeds the limit set by GDLB. If your laboratory has information that invalidates the tray, score the tray **red**. SG only recognizes W0000 as a water cup. SG treats any result with a barcode WXXXX that is not W0000 as a patient result.
 - 3) Score the tray **red** if one TQC result is outside the $\pm 3SD$ limits or two TQC are outside the $\pm 2SD$ limits.
 - 4) Score the tray **red** if the tray median is outside the acceptable range. SG scores the tray **yellow** for an APSC assay and red for any AutoDELFIAs assays. Score a tray **yellow** if on repeat the tray median is still outside the acceptable range.
 - 5) Score the tray **red** if the 2 TQC results exceed the R4s rule.
 - 6) Score the tray **green** if all TQC results are within the ± 2 SD limits or one TQC is outside the $\pm 2SD$ limits but within the $\pm 3SD$ limits.
 - 7) Score the tray **yellow** if you want additional review by GDLB’s QA system.
 - 8) Score an IRT tray **green, yellow, or red** if there is the following error message for the tray, “ALERT:Out of pipetting liquid”. The pipetting liquid is Diluent II. SG scores the tray **yellow**.
Physically verify that there was sufficient volume of Diluent II. If %CV is high for the 2 replicates of the standards and SQC or there is a change in shape of the standard curve, score the tray **red**. If all assay parameters are in, score the tray **green**.
- b. Score a tray in the **Plate** screen. A tray is scored green for released, yellow for notify (same as Held in MultiCalc), and red for prevented. To score a tray in the **Plate** screen
- 1) Select the tray from the Plate Map on the left side of the screen.
 - 2) Click ... on the tray line.
 - 3) View the **Add Flag** screen.
 - 4) Select **Free Text** or **QC-OK** from the drop down menu for **Flag Type**. There are no fixed comments at the tray level.

If all you want to do is score the tray **green**, click **QC-OK**.

Otherwise, select **Free Text**. Select from the following from the **Severity** drop down menu:

- a) Info – if you want to add a comment only
- b) Green OK - run is released
- c) Yellow Notify – run is held, same as **Held** in MultiCalc

- d) Yellow Held - requires an action to complete review and release, can change it to yellow, Notify, for further review by GDLB QA.
 - e) Red Prevented - run is prevented and must be repeated, if run is prevented, all trays and results change to **red**
 - f) Black Deleted
- 5) Enter a comment for the tray in the **Comment** box if needed. Once a comment is entered it cannot be changed or deleted. If the comment is incorrect or needs editing, write words to that effect and enter a new comment. All comments and flags are retained in the order created with the newest on top of the list.

11. Determine Result Status

Results that are presumptive positives, I-P, are blue, indeterminates for 17OHP, I-IND, are orange, and negatives, I-N, are green. Result status can be scored in the **Plate** or **Grid** screen.

- a. Use the following rules to score a result.
 - 1) Score an individual result **red** if the result for TSH, 17OHP, or IRT is **>STD**.
For rpt =1 for a high TSH, 17OHP, or IRT enter the fixed comment, **confirmed high** and score the result **green**.
For rpt = 1, if the high TSH, 17OHP, or IRT result is not confirmed, score the result **yellow** or **red** if the repeat result is invalid.
 - 2) Score an individual result **red** if the result for TSH, 17OHP, or IRT is **<STD** (or less than the low conc limit set by GDLB).
For rpt = 1, enter the fixed comment **confirmed low** and score result **green**.
For rpt = 1, if the low TSH, 17OHP, or IRT result is not confirmed, score the result **yellow** or **red** if the repeat result is invalid.
 - 3) Score an individual result **red** if the result for TSH, 17OHP, or IRT is 0.00. In addition, score any positive sample on the tray **red** and repeat to check that positive result is not due to jumping spots.
 - 4) Score an individual result **green** or **red** if the activity for TRA or BIO is low, **<~25 RFU** or **<~5 ERU**. Look for any artifact due to system, analyst, reagents, or specimen, such as an unresolved peak, no spot punched, no elution of the blood spot (eluate is clear), low Hgb area, or well not sampled by the probe. If you can identify an artifact, score the result **red**, enter a comment, and repeat. If there is no artifact and the peak is resolved, score the result **green** and report as a presumptive positive.
 - 5) Do not change the 2 results that are scored **red** by SG with the flag "duplicate barcode". The two specimens have the same barcode due to an accession error and will receive new barcodes before repeat testing. PE will delete the original accession numbers from the repeat list.
 - 6) Score a result for TRA or BIO only after looking at the peak if the SG flag is "NP-no peak found" or "UM-User modified". In the main, look for UM flag in **TRA Flag** and NP flag in **TRA Flag** or **TRB flag**. For "no peak found" the marker at peak max is red . For "user modified" the original position of the marker was changed by the analyst. As a general

rule:

- a) If the marker is at the peak maximum, score the result **green**. Enter the fixed comment **Peak OK**.
- b) If the peak is not resolved, score the result **red**.
- c) If you want GDL to review the sample, enter a comment and score the result **yellow**.

NOTE: In the main, NP and UM flags are for results with low activities. A way to find the results of low activity is to click on the column header, **BIO ERU** or **TRA-TRB RFU**, to sort by concentration. Click on **LineNr** to resort the screen to its original analytical order. This sorting can be use for all assays for any column heading.

- 7) Follow protocol to repeat an unresolved peak for TRA and BIO with water samples preceding and following the sample. For rpt=1, score the resolved peak **green** to release the result, if it is otherwise acceptable. Report any presumptive positives.
 - 8) Score a TRA result **yellow** if the TRB result is ≥ 12 and < 25 . Flag is "TrB > 12" for **TRB Flags** and **TRA-TRB Flags** and SG scores the result **yellow**. If your laboratory has information that invalidates the result, score the result **red**.
 - 9) Score a TRA result **red** if the TRB result is ≥ 25 and less < 40 . Flag is "TrB > 25" for **TRB Flags** and **TRA-TRB Flags** and SG scores the result **red**. These results should be confirmed using a different spot.
 - 10) Score a TRA result **red** if the TRB is ≥ 40 and make the specimen inadequate.
 - 11) Score every water cup, including W0000 for PQC, on the TRA or BIO run **red** if it exceeds the limits set by GDL. Limit for TRA-TRB is 20 RFU and for BIO is 8 ERU. SG scores these samples **red** and the flag is PQC+1SD.
 - 12) Score the result **red** for TRA and BIO if the Hgb pattern is High or Low Area and the run is still available for review and release. Restore the run if needed. Otherwise, enter a clear comment on the Checklist before FAXing to have GDLB QA score the result **red**. Enter the comment **High/Low Hgb** on the result line.
- b. View the chart tracings for TRA/BIO. Highlight a sample, right click, and select **View API Peak Trace**. Chart tracings go to the highlighted sample. To start at the beginning of the tracings, highlight Std B. Due to a software quirk, if you highlight Std A, chart tracings do not open.
 - c. Highlight a result in the **Result/Grid** screen, click **History** to view the sample history if needed.
 - 1) Under **Barcode** is the accession number whose sample history in on the screen.
 - 2) View the sample history in the **Answers** box. Information includes
 - Test** – names the analyte
 - Unit**
 - Value Text** – concentration
 - Status** – status can be
 - Requested** - after 1st punch, system request all other assays to complete the NBS panel

Punched – specimen is punched and waiting to be sent to a work Station

At Worklist – worklist is sent to a work station

Cancelled – original result was prevented or is unavailable, e.g., run was aborted, click **View Assay** to see the original run, click **Close** to return to sample history

Repeat Rqst – barcode is on the repeat list, waiting for repeat result

Calculated – data downloaded from instrument and concentration is available and ready for NAPS review

5 – this is applicable only to TRA/BIO, ignore the result, result is not expected, i.e., an unnecessary repeat and result will not go to SIS. For example, if TRA is prevented and BIO is released, on repeat BIO status is 5.

NOTE: SG does not have the concept of grey results. The TRA or BIO result with status 5 is black with **Unnecessary Repeat** as a flag on the worksheet. SG also does not allow a specimen to be re-punched unless it is on the repeat list.

Inspect – result is transmitted to GDLB QA

Checked – result is reviewed by GDLB QA

Accepted – result is released by GDLB QA, still waiting to be sent to SIS

Posted – result is in SIS

Time measured – is test date and time

Time accepted – date and time when GDLB QA released result

Time reported – date and time when result was sent to SIS

Determination – numeric code, 2 for negative, 49 for 17OHP indeterminate, and 50 for positive

Result Code – is positive, indeterminate, or negative

NOTE: Since the PC is not connected to SIS, there is no access to TRF Information. Ignore **Specimen**, other than accession number, and **Details**.

- d. Check **% Difference with previous** if the result is a repeat. % difference is not actionable. However if the % difference is significantly large and may be due to an error, score the result **red**.
- e. Scan the **Well** (numbers) column. If a well was deleted during punching, the entire line for the well number is missing from the worksheet.
- f. To score a result
 - 1) Highlight the well you wish to score from the plate map or highlight the result line by clicking on the **Flag** column from the grid.

NOTE: If you click on the line in a column other than **Flag** to highlight the result, right click, select **Flag** to open the **Add Flag** screen and proceed to score.

NOTE: If you are using the **Plate** view, to score correctly, be sure either **Biotinidase/BIO** or **Transferase/Analytes** is selected. If you are using the **Grid** view, to score correctly for transferase, click on or any column

- after **TRA-TRB Volts**. Otherwise you may be scoring TRB or TRA only.
- 2) Click ... on the result line.
 - 3) View the **Add Flag** screen.
 - 4) Select **Free Text**, **QC-OK**, or **Fixed Comment** from the drop down menu for **Flag Type**.

If all you want to do is scored the tray **green**, click **QC-OK**.

If you want to enter a fixed comment, select the comment and score as in 5) below. You will see the fixed comment in **Flag** and **Details in Results/Plate**.

Otherwise, select **Free Text**.

- 5) Select from the following from the **Severity** drop down menu:
 - a) Info – if you want to add a comment only
 - b) Green OK - run is released
 - c) Yellow Notify – run is held, same as **Held** in MultiCalc
 - d) Yellow Held - requires an action to complete review and release, can change it to yellow, Notify, for further review by GDLB QA.
 - e) Red Prevented - run is prevented and must be repeated, if run is prevented, all trays and results change to **red**
 - f) Black Deleted
- 6) Enter a comment for the result in the **Comment** box if needed. The comment replaces an existing flag on the grid screen. All comments and flags are retained in the order created with the newest on top of the list. An * next to the flag/comment means there are more than one. Double click on the flag/comment to see the entire list. Once a comment is entered it cannot be changed or deleted. If the comment is incorrect or needs editing, write words to that effect and enter a new comment.
NOTE: If you have a block of results you want to score the same, highlight the first result, hold down the **Shift** key and highlight the last result in the block. Score as in VII.A.11.d and do not use Add Comment as described in VII.A.9.b.5). The same score and comment show up for each result in the block.
NOTE: If you have many results that are not sequential from a run you want to score the same, highlight the first result, hold down the **Ctrl** key and highlight each result you want to include. Score as in VII.A.11.d. and not as described in VII.A.9.b.5). The same score and comment show up for each result selected.

12. Complete review and release

- a. Click **Accept** to complete review and release. You **MUST** complete review and release for biotinidase/BIO AND transferase/Analytes before you click **Accept**. Otherwise the run that was not reviewed and keeps the original SG scores.

- b. View the next screen. This shows up whenever changes were made during the review and release process. Click **Yes** when the prompt appears
Number of accepted results has changed. Do you want to recalculate to refresh statistics.
- c. Select the radio button for **Result code calculation** only when the next prompt appears
What kind of calculation do you want to perform?
Do not select **Full calculation**.
- d. Click **x** in the upper right of the screen to interrupt review and release. The prompt appears on the screen
You have made changes to the assay. Please select save to save changes and exit, discard to exit without saving or cancel to continue editing.
Click **Save** to save and exit, **Discard** to exit without saving or **Cancel** to continue review.

B. Restore a Run

1. Open the run in QA Review.
2. Click **File/Restore Assay to NAPS Review**.
3. Click **OK** when the prompt appears,
The assay will be restored to naps review.

C. Print the Repeat List

Print the repeat list at the beginning of each test day for a list of specimens that must be retested. The list contains all results prevented by your laboratory from the day before and all results prevented by GDLB QA.

1. Click **Special** (instead of Work Flow for runs) from the **Specimen Gate Result Viewer** screen. Selection available are
 - a. **Pending** – list of specimens that has been punched awaiting results
 - b. **Request List** – current local and GDLB repeat list
 - c. **Specimen Search** – search for sample history by entering accession number
 - d. **Create Worklist** – do not use
2. Click **Request List**. Use the drop down menu to select **All** for **Test**.
3. Click on the drop down menu for **Request type**. Selection available are
 - a. **Initial All** – similar to Pending
 - b. **Initial – Requested at least 2 days ago** – list of overdue repeats
 - c. **Retest – All** – contains the current local and GDLB repeat list
 - d. **Retest – Confirmation** - do not use
 - e. **Retest – QC reason** - do no use

Select **Retest – All**. Specimens are listed in order of accession number, date and time results were prevented, and the repeat test needed. The (r) after the test name means repeat.

4. Click **File/Print** and click the printer icon to print the repeat list.

D. Print the Presumptive Positive List

1. Click **Report Server** from the **Specimen Gate Result Viewer** screen.
2. Select one of the radio buttons

- o **Released Nonposted Positive Samples**
- o **Released Positive Samples on selected dates**
- o **All Positive Samples on selected date**

In general, after review and release, select **Released Nonposted Positive Samples** for a list of positives that needs to be call to the ASC. The list also includes indeterminates (Determination = Q), for 17OHP and positives for IRT that are not called to the ASC coordinator.

3. Select radio button for **NBS**
4. Click **Print**.

Send indeterminate specimens for 17OHP to GDLB when all runs are completed and released by your laboratory. Do not wait for GDL's QA decision. If you hold a run/tray, your laboratory has not completed and released all runs. Therefore, your laboratory needs to wait for QA's decision before shipping indeterminates on a run/tray held by your laboratory.

Ship via UPS for overnight delivery to GDL Monday – Thursday. Ship specimens protected with ice packs and a copy of the presumptive positive list.

E. Immediate Release to GDLB QA

Completion of review and release moves a run from NAPS Review to QA Review. All runs in QA Review are available for immediate release to GDLB QA.

1. Close the Specimen Gate Result Viewer by clicking on the x in the upper right corner.
2. Click Transfer to GDLB from the Program Menu.
3. Select the data you want to immediately send by clicking **Transfer All Data**, **Transfer TMS Data** or **Transfer NBS Data**.

NOTE: Routinely, reviewed and released runs are downloaded to GDLB QA system each night at a specific time for each laboratory.

F. View Archive Data

Click **QA Released** for all runs that have been released to SIS and follow procedures for review and release to view archive data.

G. Back up Procedures

PNS (AFP,hCG, uE3, Inh) and NBS (TSH, 17OHP, IRT, TRA, BIO, MSMS) run data are backed up every day to the internal DLT drive installed on the server. Backup procedures store all run data on DLT tape for emergency retrieval. Four tapes, labeled as Tape #1, #2, #3, and #4, are used. One tape is used for one week. Rotate the use of the tapes so that the order of use is #1, #2, #3, #4, #1, #2, #3, #4, etc. Even though backup is done every day, user intervention is required only once a week, e.g., every Friday.

1. Full backup
Do this at the server weekly, e.g., every Friday. Click **Start/Full Backup**.
2. Incremental backup
Incremental backup is performed daily without intervention/action from the

user. It is run automatically every night and it backs up all changed data from the file server to the tape. Therefore, keep the tape loaded in the DLT tape drive. No printed report will be generated from this procedure.

H. Manage Repeat List

Not available today. This is to be added in the next update of Specimen Gate.

I. Treatment of Positive and Indeterminate 17-OHP and IRT Samples

Samples that have indeterminate results for 17-OHP should be sent to GDL for 2nd tier testing. Samples that have positive results for IRT should be sent to Stanford for CF mutation analysis. Samples that are positive for both 17-OHP **and** IRT should be sent to GDL for testing, who will then send the samples to Stanford. See Appendix A for more detailed instructions.

VIII. Calculations

NA

IX. Reporting Results

- A. Identify the ASC coordinator and call to report presumptive positives on the Presumptive Positive List.

- B. Follow instructions in the Newborn Screening Accession and Reporting at the NAPS Lab Protocol.

X. Procedure Notes

NA

XI. Limitation of Procedure

NA

XII. References

Refer to newborn screening protocols.

