

Appendix 5K

Handling of Maternal Serum Specimens for Expanded Prenatal Screening Program at GDLB

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Appendix 5K

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I. Title

Handling of the Maternal Serum specimens for Expanded Prenatal Screening Program at GDLB

II. Principle

GDLB has established a maternal serum specimen collection for the purpose of method development and validation, program-related studies, and training. The source of these biological specimens are maternal serum samples from the State of California Expanded Prenatal Screening Program. GDLB determines type of specimens needed for a special study. This protocol details steps on generating expected list, receipt, handling, storing and disposal of specimens after use.

III. Specimen Collection and Type

A. Definition of Specimens

Specimens are maternal serum in serum separator tubes after completion of PNS panel testing at the NAPS laboratories.

B. Specimen types, based on purposes of usage, are:

1. First trimester specimen- for establishing New Biomarker median
These are specimens that are drawn too early for the 2nd trimester screening and fall within week 9 to13 of gestation. These specimens will be used for setting pregnancy associated plasma protein- A (PAPP-A) and other New Biomarker for Prenatal screening of Down syndrome.
2. Down syndrome screening positive specimen – for determining efficacy of New Biomarker screening
Specimen that were screening positive for Down syndrome either by Quadruple or Triple markers method.
3. Maternal serum specimens screening samples- for making Proficiency Panel and Reference Panel sample pools
Specimens that are drawn too late for 2nd trimester or too early for 1st trimesters have unique concentration of Biomarkers. They can be diluted with male serum to make maternal serum pools at various concentration levels for existing PNS panels or for new method development.
4. Maternal serum specimens, general- for kit lot and assay verification and for training
Specimens more than 30 days old are used in the new kit lot verification study. The purpose is to verify the median rule in use is applicable to the new lot.
5. Maternal serum specimens, special- for special study
Specimens that met specified criteria for special study such as low uE3, Possible EDTA are retrieved for special study.
6. Maternal serum specimen, investigation- to determine validity of the test result

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These are specimens that have questionable results identified by RS IV or GDSP-PDES.

7. Misdirected or lost maternal serum specimens

These maternal serum specimens may be sent to GDLB by mistake or redirected to GDLB when it was lost in mail.

IV. Equipment and Supplies

- A. Shipping containers
- B. Cold packs
- C. Dry ice shipping labels
- D. Color marking pens
- E. Sample tube racks
- F. Computer access to Q and G drive
- G. Excel software

V. Reagents-Not Applicable

VI. Calibration and Quality Control-Not Applicable

VII. Procedures

A. Generating the list

1. First trimester specimen

PDES-GDSP section generates the specimens availability list every two weeks and posts the list on Q:\ PRENATAL report\ 1st trimester samples. The list started from January 2006 and will continue until we have enough specimens for each gestation week.

Down syndrome (DS) screening positive specimen – for determining efficacy of quadruple marker screening

PDES-GDSP section generates the list every two weeks and posts the list on Q drive\PRENATAL report\ DS positive. GDLB RS III or RS II is responsible to edit the list and redistribute the list to individual NAPS for specimen retrieval.

2. Late 2nd trimester specimens

PDES-GDSP section generates the list every two weeks and posts the list on Q:\ PRENATAL report\ High pool (Late 2nd trimester for high Inhibin A). GDLB RS III or RS II is responsible to edit the list and redistribute the list to individual NAPS for specimen retrieval.

3. Maternal serum specimens-general

Chemist, under the direction of RS IV or Supervising Chemist, will retrieve large number of 30 days old maternal serum samples for validation and training.

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This is a bulk shipment of old maternal serum samples without a list of accession number.

4. Maternal serum specimens, special
RS IV or Supervising Chemist will define the criteria for special study purpose. RS IV or Supervising Chemist will generate the list or provide criteria to NAPS supervisor, who would save and send the specimens to GDLB. This list is for short-term use only and the number of specimen varied.
- 5 Maternal serum specimen, investigation
RCC or supervising Chemist will provide NAPS laboratory the accession number(s) of the specimen to be sent to GDLB for investigation.
- 6 Lost or misdirected maternal serum specimen
No expected list.

B. Retrieving the specimens from NAPS laboratories

Person initiating specimen retrieval must fill out the Request of Maternal Serum Specimen Form. The Form should be faxed to NAPS laboratory at least one day before scheduled shipment date.

i. First trimester specimen

The list of first trimester specimens was sent to NAPS laboratory by GDSP when the list was generated. NAPS laboratory has been instructed to pull the first trimester specimens and stored in freezer for 30 days, until GDLB called for the specimens. This has been on going since Jan 2006 and will continue at least one year. GDLB RS III or RS II is responsible to edit the list and redistribute the list to individual NAPS for specimen retrieval.

Lab assistant will fax Retrieval Request Form with the expected specimens list to NAPS laboratories and send shipping containers and dry ice as needed. Supervising laboratory assistant will devise specimen retrieval schedule based on the workload.

ii. Down syndrome (DS) positive specimen

GDLB will retrieve specimens when New Biomarker is studied. GDLB RS IV or RS III is responsible to edit the list and redistribute the list to individual NAPS for specimen retrieval.

iii. Late 2nd trimester specimens

Follow the same procedure as the first trimester specimens.

iv. Maternal serum specimens-general

PNS analyst will submit Specimen Retrieval Request to Supervising Lab assistants. Supervising Lab assistant will contact NAPS supervisors and retrieve the specimens either by overnight shipment or by sending a

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laboratory assistant to NAPS laboratory to bring back the specimen to GDLB.

v. Maternal serum specimens, special

RS III or Supervising Chemist will fill out Specimen Retrieval Request Form and submit to Supervising Lab assistant to manage the retrieval of requested specimens.

vi. Maternal serum specimen, investigation

RS III or Supervising Chemist will fill out Specimen Retrieval Request Form and submit to Supervising Lab assistant to manage the retrieval of requested specimens.

vii. Lost or misdirected maternal serum specimen.

Specimens belong to this category arrives GDLB unexpectedly. It happens occasionally.

b. Receipt of maternal serum samples at GDLB

Upon specimen arrival at GDLB, verify that specimens received will match to the information on the Request of Retrieve Specimen Form. Record the condition of specimens and temperature of the package. Store in freezer or refrigerator per storage condition specified on the Request Form by the person requesting the specimens

c. Handling of maternal serum specimens at GDLB

i. First trimester specimen

The inspecting and sorting steps can be performed anytime after receipt of specimens.

1. **Make sure specimen are kept frozen.** Take out specimen one lab at a time. Use the first trimester specimen list, which indicate gestational age for each sample, mark sample tube per gestational week with different color code using HI-Liter marker pen as indicated below.

9th—Red, 10th—Green, 11th --Pink, 12th –Orange, 13th—Blue and 14th—Purple.

2. Write on the list “no tube”, when little or no serum left.
3. Store specimens in designated location in freezer by laboratory and by the order of list generated.
4. When completion, enter as missing tube or QNS information into the first trimester specimen database.

ii. Down syndrome (DS) positive specimen

For each DS positive specimen, there is 1 or 2 accompanying negative specimens that should be collected at the same time. Mark only the positive specimen Yellow with Hi-Liter marker Pen.

Store in designated freezer until testing.

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- iii. Late 2nd trimester specimens
No color coding needed Same procedure as the 1st trimester specimens.
 - iv. Maternal serum specimens-general
No special handling of the specimens. Inform person who requests the specimens when the specimens arrive. Give the Specimen Request Form to the person. Store the specimens at the designated location per instruction from the requested person
 - v. Maternal serum specimens, special
No special handling of the specimens. Inform person who has requested specimens when the specimens arrive. Give the Specimen Request Form to the person. Store the specimens at the designated location per instruction from the requested person.
 - vi. Maternal serum specimen, investigation
No special handling of the specimens. Inform person who has requested specimens when the specimens arrive. Store specimen in the refrigerator in the PRENATAL laboratory. If specimen is still frozen, place it in freezer.
 - vii. Lost or misdirected maternal serum specimen
Place in the refrigerator in the specimen receiving room. Follow instruction per Redirection of PRENATAL samples in GDLB Accession Directory .
- d. Storage of maternal serum specimens at GDLB
- i. First trimester specimen
Store in designated freezer in PRENATAL lab, Room 263 until testing. Bring specimens to PRENATAL room and store in refrigerator for overnight thawing before testing. Discard after testing.
 - ii. Down syndrome (DS) positive specimen
Store in designated area in walk-in freezer, Room 228 or freezer in PRENATAL lab until testing. Bring specimens to PRENATAL room and place in refrigerator for overnight thawing before testing. Discard after testing.
 - iii. Late 2nd trimester specimens
Store in designated freezer in PRENATAL lab, Room 263 until testing. Bring specimens to PRENATAL room and store in refrigerator for overnight thawing before testing. Discard after testing.
 - iv. Maternal serum specimens-general
Store maternal serum specimens in walk-in freezer until testing.
 - v. Maternal serum specimens, special

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Store maternal serum specimens in the freezer in C-263 until testing.

- vi. Maternal serum specimen, investigation
Store maternal serum specimens in the freezer or refrigerator per instruction on the request form until testing.
- vii. Lost or misdirected maternal serum specimen
Store specimen in refrigerator until redirected.
- e. Disposal of maternal serum specimens at GDLB
Discard all specimens after testing unless special request to save the specimens is indicated on the Request Form.
- f. Record Keeping
 - i. Data Base File in Excel
1st trimester, DS positive and Late 2nd trimester specimens lists that are generated by GDB are converted to Excel file and stored in sub file under G:\MMPS. RS III is responsible for maintaining and update this excel file.
 - ii. Request for Maternal Serum Specimen Form
Forms are kept in PRENATAL lab and also in Specimen receiving Room. Tien Dang is responsible for filing the forms and checking the timely disposal of the used specimens in PRENATAL lab.

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ATTACHMENT A
Request for Maternal Serum Specimen Retrieval

To: _____ (Lab Name) Requested by _____ Date _____

Expected List attached [] Yes or [] No

- Type of specimens requested
- () 1st Trimester maternal serum specimens
 - () Down Syndrome screening positive specimens
 - () Late 2nd trimester MS specimens
 - () PRENATAL specimens, General , No. of samples _____
 - () PRENATAL specimens, Specific , Specify _____
 - () PRENATAL specimens, Investigation
 - () Others. Specify _____

Shipment condition: () with dry ice Date shipped to GDLB _____
 () with ice pack
 () none

For NAPS Use only

If you have questions, call Donald Cockerham at 510 231-1734.

Date of shipment _____ Shipment by _____

For Prenatal specimen with expected list, enclosed the list. Write "no tube" on the list if you cannot find the specimen.

For Prenatal specimens, specific: # of specimens _____ and accession dates. _____

For Prenatal specimens, general: # of specimens _____ and accession dates _____

Comments _____

For GDLB Use only

Date of Receipt _____ Person Receiving _____

- Condition of specimens
- () Frozen
 - () Cold
 - () Warm

Specimen stored at _____ (Location, room #, refrigerator or freezer)

Person who log in specimen _____ Is the requester notified (Yes/No) _____

Date tested or used _____ Date specimens disposed _____

Authorization to retain specimens longer than 12 months at GDLB _____