CMBP Maternal Serum Question Set and Test Cases
First and Second Trimester

The CMBP Test Case phase is initiated once the Electronic Data Analysis (EDA) structure has been verified. Completion of the testing phase will ensure that AFP orders can be submitted to Labcorp electronically.

Labcorp's Center for Molecular Biology and Pathology (CMBP) laboratory has developed scenarios to validate the "laboratory" related text context for interfaces. The scenarios in this document were created for that purpose and may not reflect how clinicians will enter information.

Copies of either a manifest or a requisition are required in addition to screen shots of the order entry screens when applicable for issue resolution. A New Development Certification (NDC) Analyst will review the documents prior to initiating the final testing/review phase with CMBP.

Gestational Dating Criteria:

Gestational options are Last Menstrual Period (LMP) Date, Estimated Date of Delivery Date (EDD), Weeks and Days on Date (format – NN weeks N days) and Decimal (format – NN.N). Submit only **ONE** gestational method per order.

Date Fields:

Date fields include Crown Rump Length (CRL) on Date, Gestational Age on Date; LMP Date and EDD/EDC Date. Various test scenarios indicate using specific guidelines, a date in the past, today's date or a 6-month future date. For testing purposes ANY dates provided may be arbitrary and are not required to reflect clinical accuracy.

Note:

If the client or vendor does not use or support a specific gestational age criterion or test codes listed in the test plan you may substitute or omit the criteria, method or test code(s) used by the client or vendor. It is imperative to document any deviations from the scenarios detailed in the test plan. (Example: Test scenario specifies LMP Date; however, client only uses EDD Date; client or vendor will not order specific tests.)

CMBP Test Cases

First and Second Trimester

Test Case 1 (First Trimester w/NT)

Maternal Serum Testing: Nuchal Translucency

Patient Name	TEST, AFPONE
DOB	1/1/1990
Order Code	017500
Insulin Dependent	Yes
Race	White/Caucasian
Ethnicity	Hispanic or Latino
Weight (lbs)	180
Number of fetuses	2
Other Indications	Yes
Additional Information	Bleeding
Previously Elevated AFP	Yes
Ultrasound Measurement of Crown Rump Length (mm)	75.0
Ultrasound Measurement Crown Rump Length Date	Today's Date/Past Date
Ultrasound Measurement Crown Rump Length Twin B (mm)	60.0
Nuchal Translucency	1.5
Nuchal Translucency for Twin B	1.4
Donor Egg	Yes
Age of Donor Egg	21
Prior Down Syndrome/ONTD screening during current pregnancy	Yes
Prior First Trimester Testing	Yes
Prior Second Trimester Testing	Yes
Family History of NTD	Yes
Prior Pregnancy with Down Syndrome	Yes
Chorionicity – Monochorionic (Twins Only)	Yes
Chorionicity – Dichorionic (Twins Only)	Not Selected
Chorionicity – Unknown (Twins Only)	Not Selected
Sonographer Last Name	Test
Sonographer First Name	Sample
Sonographer ID Number	GH7890
Credentialed by NTQR	Yes
Credentialed by FMF	Not Selected
Credentialed by Other Organization	Not Selected
Site Number	AB1234
Reading Physician	ZZ1234

CMBP Test Cases
First and Second Trimester
Test Case 2 (Integrated 1)

Maternal Serum Testing: Nuchal Translucency

Patient Name	TEST, AFPTWO
DOB	1/1/1990
Order Code	017100
Insulin Dependent	No
Race	Other Race
Ethnicity	Not Hispanic or Latino
Weight (lbs)	361
Number of fetuses	2
Other Indications	No
Additional Information	Not Selected
Previously Elevated AFP	Yes
Ultrasound Measurement of Crown Rump Length (mm)	75.0
Ultrasound Measurement Crown Rump Length Date	Today's Date/Past Date
Ultrasound Measurement Crown Rump Length Twin B (mm)	Not Selected
Nuchal Translucency	1.5
Nuchal Translucency for Twin B	Not Selected
Donor Egg	No
Age of Donor Egg	Not Selected
Prior Down Syndrome/ONTD screening during current pregnancy	No
Prior First Trimester Testing	No
Prior Second Trimester Testing	No
Family History of NTD	No
Prior Pregnancy with Down Syndrome	No
Chorionicity – Monochorionic (Twins Only)	Not Selected
Chorionicity – Dichorionic (Twins Only)	Yes
Chorionicity – Unknown (Twins Only)	Not Selected
Sonographer Last Name	Test
Sonographer First Name	Sample
Sonographer ID Number	GH7890
Credentialed by NTQR	Yes
Credentialed by FMF	Not Selected
Credentialed by Other Organization	Not Selected
Site Number	AB1234
Reading Physician	ZZ1234

CMBP Test Cases

First and Second Trimester

Test Case 3 (Integrated 2)

Maternal Serum Testing: Nuchal Translucency

Patient Name	TEST, AFPTHREE
DOB	1/1/1990
Order Code	017170
Insulin Dependent	No
Race	Black OR African American
Ethnicity	Unknown
Weight (lbs)	150
Number of fetuses	2
Other Indications	No
Additional Information	Not Selected
Previously Elevated AFP	Yes
Ultrasound Measurement of Crown Rump Length (mm)	75.0
Ultrasound Measurement Crown Rump Length Date	Today's Date/Past Date
Ultrasound Measurement Crown Rump Length Twin B (mm)	Not Selected
Nuchal Translucency	1.5
Nuchal Translucency for Twin B	Not Selected
Donor Egg	No
Age of Donor Egg	Not Selected
Prior Down Syndrome/ONTD screening during current pregnancy	No
Prior First Trimester Testing	No
Prior Second Trimester Testing	No
Family History of NTD	No
Prior Pregnancy with Down Syndrome	No
Chorionicity – Monochorionic (Twins Only)	Not Selected
Chorionicity – Dichorionic (Twins Only)	Not Selected
Chorionicity – Unknown (Twins Only)	Yes
Sonographer Last Name	Test
Sonographer First Name	Sample
Sonographer ID Number	GH7890
Credentialed by NTQR	Not Selected
Credentialed by FMF	Not Selected
Credentialed by Other Organization	Yes
Site Number	AB1234
Reading Physician	ZZ1234

CMBP Test Cases
First and Second Trimester
Test Case 4 (Sequential 1)

Maternal Serum Testing: Nuchal Translucency

Patient Name	TEST, AFPFOUR
DOB	1/1/1990
Order Code	017700
Insulin Dependent	No
Race	Asian
Ethnicity	Unknown
Weight (lbs)	190
Number of fetuses	2
Other Indications	Yes
Additional Information	Multiple Miscarriages
Previously Elevated AFP	Yes
Ultrasound Measurement of Crown Rump Length (mm)	75.0
Ultrasound Measurement Crown Rump Length Date	Today's Date/Past Date
Ultrasound Measurement Crown Rump Length Twin B (mm)	60.0
Nuchal Translucency	1.5
Nuchal Translucency for Twin B	1.4
Donor Egg	Not Selected
Age of Donor Egg	Not Selected
Prior Down Syndrome/ONTD screening during current pregnancy	Not Selected
Prior First Trimester Testing	Not Selected
Prior Second Trimester Testing	Not Selected
Family History of NTD	Not Selected
Prior Pregnancy with Down Syndrome	Not Selected
Chorionicity – Monochorionic (Twins Only)	Not Selected
Chorionicity – Dichorionic (Twins Only)	Not Selected
Chorionicity – Unknown (Twins Only)	Not Selected
Sonographer Last Name	Test
Sonographer First Name	Sample
Sonographer ID Number	GH7890
Credentialed by NTQR	Not Selected
Credentialed by FMF	Not Selected
Credentialed by Other Organization	Yes
Site Number	AB1234
Reading Physician	ZZ1234

CMBP Test Cases

First and Second Trimester

Test Case 5 (AFP Tetra)

Maternal Serum Testing: Nuchal Translucency

Patient Name	TEST, AFPFIVE
DOB	1/1/1990
Order Code	017319
Insulin Dependent	No
Race	Not Indicated
Ethnicity	Not Hispanic OR Unknown
Weight (lbs)	999
Gestational Age (Weeks)	21
Gestational Age (Days)	5
Gestational Age (Decimal)	Not Selected
Gestational Age Date of Calculation	Today's Date/Past Date
GA Calculation Method (LMP)	LMP
LMP Date	Not Selected
GA Calculation Method – Ultrasound	Not Selected
GA Calculation Method – EDD/EDC	Not Selected
EDD/EDC Date	Not Selected
Number of fetuses	2
Other Indications	No
Additional Information	Not Selected
Previously Elevated AFP	No
Donor Egg	Yes
Age of Donor Egg	30
Prior Down Syndrome/ONTD screening during current pregnancy	Not Selected
Prior First Trimester Testing	Not Selected
Prior Second Trimester Testing	Not Selected
Family History of NTD	Not Selected
Prior Pregnancy with Down Syndrome	Not Selected

CMBP Test Cases

First and Second Trimester

Test Case 6 (Maternal Serum AFP)

Maternal Serum Testing

Patient Name	TEST, AFPSIX
DOB	1/1/1990
Order Code	010801
Insulin Dependent	Not Selected
Race	Native Hawaiian
Ethnicity	Not Selected OR Unknown
Weight (lbs)	150
Gestational Age (Weeks)	Not Selected
Gestational Age (Days)	Not Selected
Gestational Age (Decimal)	Not Selected
Gestational Age Date of Calculation	Not Selected
GA Calculation Method (LMP)	Not Selected
LMP Date	Not Selected
GA Calculation Method – Ultrasound	Not Selected
GA Calculation Method – EDD/EDC	Not Selected
EDD/EDC Date	Today's Date/6 Month Future Date
Number of fetuses	Not Selected
Other Indications	No
Additional Information	Not Selected
Previously Elevated AFP	No
Donor Egg	No
Age of Donor Egg	Not Selected
Prior Down Syndrome/ONTD screening during current pregnancy	Yes
Prior First Trimester Testing	Yes
Prior Second Trimester Testing	Yes
Family History of NTD	Yes
Prior Pregnancy with Down Syndrome	Yes

CMBP Test Cases

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Test Case 7 (Maternal Serum AFP)

Maternal Serum Testing - Expanded

Patient Name	TEST, AFPSEVEN
DOB	1/1/1990
Order Code	010801
Insulin Dependent	Not Selected
Race	Black OR African American
Ethnicity	Not Selected OR Unknown
Weight (lbs)	150
Gestational Age (Weeks)	Not Selected
Gestational Age (Days)	Not Selected
Gestational Age (Decimal)	16.9
Gestational Age Date of Calculation	Today's Date/Past Date
GA Calculation Method (LMP)	Not Selected
LMP Date	Not Selected
GA Calculation Method – Ultrasound	Not Selected
GA Calculation Method – EDD/EDC	Not Selected
EDD/EDC Date	Not Selected
Number of fetuses	Not Selected
Other Indications	No
Additional Information	Not Selected
Previously Elevated AFP	No
Donor Egg	Yes
Age of Donor Egg	30
Egg Donor Type	Self
Prior Down Syndrome/ONTD screening during current pregnancy	Yes
Prior First Trimester Testing	Yes
Prior Second Trimester Testing	Yes
Family History of NTD	Yes
Prior Pregnancy with Down Syndrome	Yes

CMBP Test Cases

First and Second Trimester

Test Case 8 (Maternal Serum AFP)

MaterniT21 PLUS Core+ESS

Patient Name	TEST, AFPEIGHT
DOB	1/1/1990
Order Code	451931
Insulin Dependent	No
Race	Black OR African American
Ethnicity	Not Selected OR Unknown
Weight (lbs)	150
Gestational Age (Weeks)	15
Gestational Age (Days)	3
Gestational Age in Decimal Form	Not Selected
Gestational Age Date of Calculation	Not Selected
GA Calculation Method	EDD
EDD/EDC Date	Not Selected
LMP Date	Not Selected
Number of Fetuses	3
Other Indications	No
Additional Information	Not Selected
Previously Elevated AFP	No
Donor Egg	Yes
Age of Egg Donor	42
Type of Egg Donor	Non-Self
Prior Down Syndrome/ONTD screening during current pregnancy	Yes
Prior First Trimester Testing	Yes
Prior Second Trimester Testing	Yes
Family History of NTD	Yes
Prior Pregnancy with Down Syndrome	Yes
Advanced Maternal Age	Yes
Positive Maternal Serum Screening Test	Yes
Previous Pregnancy with Aneuploidy	No
Family History of Chromosomal Abnormality	Yes
Ultrasound Finding	Yes
Balanced Robertsonian Translocation	Yes
Pretest Counseling	Yes
Cell-Free DNA Testing	No

Maternal Serum Question Set and Glossary

The following is not intended to replace or override the contents of the External EDI Specifications for Reference Lab Interfaces. The following information is provided to avoid potential sources of confusion.

Required Order Entry (O/E) fields are determined by test code and fall into one of 3 groups: Group 1 – Maternal Serum Testing: Nuchal Translucency (NT), Group 2 – Maternal Serum Screening without NT, and Amniotic Fluid or AFP. Historically, screening included only groups 2 and 3. However, the American College of Obstetricians and Gynecologists recommended that group 1 tests be made available to all pregnant women. The tests ordered will depend on provider and patient preferences in addition to trimester phase.

It is recommended that all fields be built and made available to accommodate the evolving changes in maternal serum screening.

Order Codes by Group			
Group 1 – MSSNT	Group 2 – MSONLY	Group 3 – AFAFP	Group 4 – SEQUE1
017500 1ST Trimester w/NT **017100** Integrated 1 **017170** Integrated 2 **017700** Sequential 1 **017750** Sequential 2	**017319** AFP Tetra **010801** AFP, Open Spina Bifida Group 2 - SERIN **017200** Serum Integrated 1 **017270** Serum Integrated 2	**002428** AFP, Amniotic Fluid **510185** Chromosome, Amniotic Fluid **511580** Chromosome, AFP/AChE/HbF **510305** AFP/AChE/HbF Amniotic Fluid	**451927** MaterniT21 PLUS Core **451931** MatrniT21 PLUS Core+ESS **451934** MaterniT21 PLUS Core+SCA **451937** MaterniT21 PLUS Core+SCA+ESS **451941** MaterniT Genome **451951** MaterniT21 PLUS Core NO Gender

Making all dating segments available is preferred since physicians may date patients differently, even within the same office. If an account **ALWAYS** uses specific dating criteria, for example, 3.2 and 5.2, it is acceptable to build only those fields. Please state this when submitting the test cases.

Responses should be sent in OBX segments. ZSA/Z segments are backwards compatible. ZSA 2.4 represents the date when the gestational age was determined. Gestational age on date does not have to be, and **often is not**, the same as the specimen date or the ultrasound date.

> **Example:** Test code 017319 requires a patient to be 15.0-21.9 weeks on the date of draw. The physician submitted that the patient was 6 weeks 5 days on July 1, 2025, with a specimen date of Sept 9, 2025. The internal system calculator will determine the gestational age using the information provided. In this example, the Order Entry (OE) fields populated would be 2.1, 2.2 and 2.4 with 6 weeks, 5 days, and 07/01/2025, respectively.

ZSA 2.4 should never default to the specimen date. The only possible exception would be if an account will **ALWAYS** provide the gestational age the patient is **on the specimen date**. Even then, it is safer to require ZSA 2.4 manually populate and not default.

GA Calculation **Method** has 3 options: LMP, EDD or Ultrasound. Even though calculation method is divided into three separate fields (ZSA3.1, ZSA4.1, ZSA5.1), it can be displayed as a single question with three options. It does not require that an LMP date, an EDD date, or an Ultrasound date be provided. If not populated, a null/blank value should be submitted. The accuracy of dating may vary depending on the method. CMBP utilizes this information in making recommendations related to abnormal results and in performing Quality Assurance.

Example 1:

Specimen date: 9/9/25

Gest Age: 16.0 weeks

On Date: 9/2/25

Method: LMP

In the above example, the patient's LMP date is not needed. Based on the given information, the patient was 16.0 weeks on 9/2. The doctor calculated the gestational age by using the last menstrual period date.

Example 2:

Method: EDD

EDD DATE: 04/04/2025

The internal calculator will determine the gestational age on the date of draw using the above information.

Example 3:

Method: LMP

EDD DATE: 04/04/2025

The physician determined the EDD based on the patient's LMP date.

Notes:

***Submit gestational age in **one** format only: weeks and day **OR** decimal. See below for decimal age conversion.

DECIMAL AGE in 1/10 week:

1 day = 0.1

2 days = 0.3

3 days = 0.4

4 days = 0.6

5 days = 0.7

6 days = 0.9

****A hierarchy is used when multiple gestational ages/methods are submitted. The hierarchy is as follows (exception of Serum Integrated 1)

Gestational Method Hierarchy

Ultrasound

LMP

EDD/EDC

Given

Hierarchy for Serum Integrated 2

CRL

EDD

US

LMP

Given

Additional Requirements for AOEs and Patient Demographics

- Submit patient's race in PID10. Check specifications for valid codes.
- Patient Weight (lbs) should be submitted via HL7 in ZCI-2 or OBX.
- All order entry questions with a response of 'YES' or 'NO' should provide a field for YES, a field for NO and should default to Blank. The fields on the requisition should be able to capture 3 possible responses: YES, NO, and blank if not answered.

Maternal Serum Question Set

Glossary

LMP: Last menstrual period. Given as the first day of the patients last menstrual cycle. As a rule of thumb, conception typically occurs approximately 2 weeks after this date, so it can be used to ESTIMATE how far along a patient is in their pregnancy.

EDD/EDC: Estimated Date of Delivery (archaic term is estimated date of confinement). This is a patient's DUE DATE. A pregnancy averages 280 days in length.

Crown Rump Length: Commonly abbreviated "**CRL**." This is a measurement of the fetus obtained using ultrasound. As the name implies, it is the length of the fetus from the crown of fetal head to the tailbone, or rump. The CRL is the most accurate estimate of gestational age when measured in the first 13 weeks of pregnancy.

Nuchal Translucency: Commonly abbreviated "**NT**." is a fluid filled area found in the neck region of the fetus that can be measured on ultrasound. Group 1 tests require that an NT measurement be obtained by the client and provided to the laboratory. The NT is often larger than normal in pregnancies with certain birth defects. The NT measurement is combined with analysis of the blood sample to calculate the risk for certain birth defects. The NT is measured on ultrasound; the crown rump length is also measured. CRL length (along with the CRL date) is the only dating criteria accepted for test cases 1-4. Sonographers must be certified specifically in obtaining NT measurements. Sonographer information is required on the O/E screen to confirm that the sonographer is NT certified.

Chorionicity: Used only for twin pregnancies. Chorion is a membrane that surrounds the fetus. A twin pregnancy can represent identical twins or fraternal (non-identical) twins. It is important to know if the twins are identical or fraternal when performing a risk assessment. Sometimes on ultrasound, a physician can determine in a twin pregnancy if there is only one chorion (monochorionic and always identical twins) or two chorions (dichorionic and usually fraternal twins). This information is used in the risk assessment for twins if provided.