Comprehensive Manual for Nuchal Translucency (NT) Practitioners

Updated
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California Department of Public Health
Genetic Disease Screening Program

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State of California Department of Public Health
Genetic Disease Screening Program
850 Marina Bay Parkway, Richmond, CA 94804

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Change Log

	Page/Section	Current Release/Revision Date
Version 1: Initial Release		March 2009
Version 2: Significant Changes • NT Data Entry Staff – Access to SIS… • NT Exam Findings/Fetal Demise…	 Chapter 2 Section 2.2 Chapter 4 Section 4.3	July 2010
Version 3: Significant Changes • "Full Integrated Screening" has been renamed "Sequential Integrated Screening." • Cases with a Large NT (≥3.0 mm) are now "Large NT: Screen Positive" with risk assessment and follow-up options distinct from other "Screen Positive" cases. • Data input for twin pregnancies has been expanded to include "Unable to Measure" fields for Fetus A.	Throughout manual	April 2011
Version 4: Significant Changes • A pregnancy with a triplet to twin fetal demise is screenable.	Chapter 4 Section 4.3	November 2012
Version 5: Significant Changes • Fetal echocardiogram is no longer offered as a follow-up option covered by the Program.	Throughout manual	October 2013
Version 6: Significant Changes • Noninvasive Prenatal Testing (NIPT) is offered as a follow-up option covered by the Program for patients who are Screen Positive.	Throughout manual	November 2013
Version 7: Significant Changes • Trisomy 18 Screen Positive cutoff changed from 1 in 50 to 1 in 150.	Throughout manual	February 2016
Version 8: Significant Changes • NT Screen Positive cutoff changed from ≥3.5 mm to ≥3.0 mm.	Chapter 4 Section 4.3	November 2016

Table of Contents

List of Figures

List of Tables

Additional Summary Instructions in the Handbook for Nuchal Translucency (NT) Practitioners:

- Entering NT Exam Data in the Prenatal Screening Program
- SIS Messages and Status Indicators
- Twin Pregnancies and Other Findings in NT Exams
- Scheduling NT Exams and Blood Draws to Facilitate SIS Data Entry
- Gestational Age Dating based on the NT Exam Data
- Viewing and Communicating Your Patient's Prenatal Screening Result Interpretation
- Contacting the Prenatal Screening Program

Chapter 1: Nuchal Translucency and the California Prenatal Screening Program

1.1 Introduction

The California Prenatal Screening Program (the Program) offers all pregnant women in California the opportunity to have prenatal screening for certain birth defects. This manual is a resource for Nuchal Translucency (NT) Practitioners participating in the Program.

The Program continues to evolve to incorporate new methods of screening. In March 2009, the California Prenatal Screening Program expanded to include first trimester screening. This expansion allowed the Program to provide pregnant women a risk assessment for Down syndrome and Trisomy 18 earlier in pregnancy and to provide more accurate risk assessment in the second trimester of pregnancy.

In April 2011, the Program added a new Screen Positive risk interpretation based on a large (≥ 3.0 mm) Nuchal Translucency measurement. The pregnancies identified as ***Large NT: Screen Positive*** have a greater than 1 in 5 risk for chromosomal and cardiac abnormalities and are eligible for follow-up services.

The California Prenatal Screening Program now includes:

- First trimester analytes and optional Nuchal Translucency measurements
- First trimester screening for Down syndrome, Trisomy 18, and, when the NT ≥ 3.0 mm, additional chromosomal abnormalities.

Under the expanded Program, pregnant women are offered five screening options. These options are discussed on the next page. Gestational age windows for valid first and second trimester blood specimen collection and NT exam are shown in Figure 1.1.

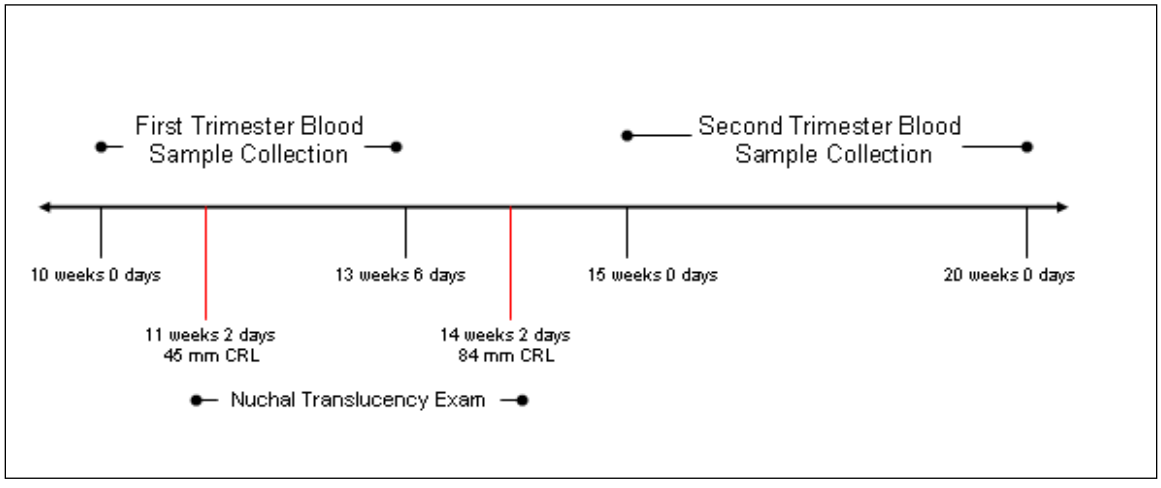


Figure 1.1: Gestational Age Windows for Blood Specimen Collection and NT Exam

1.1.1 First Trimester Combined Screening

Women may undergo a first trimester blood test and an NT exam to obtain the earliest risk assessment for Down syndrome and Trisomy 18. Whether this Preliminary Risk Assessment is ***Screen Negative*** or ***Screen Positive***, the woman may participate in a second trimester blood test to obtain a refined risk assessment for Down syndrome and Trisomy 18 (Sequential Integrated Screening) and to be screened for neural tube defects and Smith-Lemli-Opitz syndrome (SCD).

1.1.2 Sequential Integrated Screening

Women may undergo a first trimester blood test and an NT exam followed by a second trimester blood test for Sequential Integrated Screening. Sequential Integrated Screening provides the most accurate risk assessment for Down syndrome and Trisomy 18.

1.1.3 Serum Integrated Screening

Women who submit blood specimens in the first and second trimester, but who do not have an NT ultrasound, will receive Serum Integrated Screening. No risk assessment will be provided in the first trimester.

1.1.4 Quad/Quad-NT Screening

For women who do not submit a blood specimen in the first trimester, the Program still offers Quad Screening based on a second trimester blood specimen. The addition of NT information to the second trimester blood analysis increases the accuracy of Quad Screening for Down syndrome and Trisomy 18.

1.1.5 NTD/SCD Screening

Women who have had chorionic villus sampling (CVS) and submit a blood specimen in the second trimester will receive a risk assessment for neural tube defects (NTDs) and Smith-Lemli-Opitz syndrome (SLOS) only.

Under each screening scenario, women who receive a ***Screen Positive*** or a ***Large NT: Screen Positive*** result are offered a range of options for follow-up at no additional cost, including genetic counseling and authorized diagnostic procedures.

1.2 NT Practitioner Prenatal Screening Program Participation

NT Practitioners (NTPs) must be credentialed by the Nuchal Translucency Quality Review (NTQR) or the Fetal Medicine Foundation (FMF) and registered with GDSP to participate in the Program. Data submitted by unregistered practitioners will not be used for risk interpretation or gestational dating.

If your credential status changes from “active” to “in remediation,” you may still participate in the Program; however, you must work directly with your credentialing program to regain “active” status. If your credential status changes to “inactive,” data you submit will not be used for risk interpretation or gestational dating. The credentialing agencies can answer questions about credential status or whether an

NTP is registered with the State. Contact information for NTQR, FMF, and GDSP are included in Chapter 5.

The Prenatal Screening Program does not provide reimbursement for the NT exam. The exam should therefore be billed to the patient's primary insurance carrier.

1.3 Purpose of This Manual

The purpose of this manual is to introduce NT Practitioners to the Prenatal Screening (PNS) Program, to familiarize practitioners with the web interface for the Program's Screening Information System (SIS), and to provide them with training and support necessary to participate in the PNS Program. The manual includes:

- Explanation of the role of NT data in the PNS Program and discussion of how to facilitate participation in the Program.
- Instructions on how to enter NT data directly into SIS or provide data to referring clinicians.
- Examples of results and interpretations.
- A description of the disclosure of first trimester risk interpretations and options for follow-up with ***Screen Positive*** patients.
- Communication of NT exam findings.
- Additional information on PNS Program participation.

In addition to this Comprehensive Manual, there are several quick reference guides available for NT Practitioners. These resources are located on the NT Practitioner webpage along with other tools.

1.4 NT Exam Data and Gestational Age Dating in the PNS Program

Correct interpretation of screening results depends on accurate gestational dating. In addition, blood specimens must be drawn during a specific gestational age window. Gestational dating of a pregnancy within the Program is based on the Crown-Rump-Length measured at the time of the NT exam (NT-CRL) if available. The NT-CRL is converted to a gestational age using the Hadlock (*Radiology* 1992; 182:501-505) conversion table. If no NT-CRL is available, a pregnancy is dated based, in order of priority, on an ultrasound exam, Last Menstrual Period (LMP), or physical exam.

Although in clinical practice a difference in gestational dating of several days may not be reflected in a patient's chart, SIS uses the gestational age from the highest priority dating method available to date a pregnancy. Blood draws for screening purposes should therefore be scheduled based on the NT-CRL converted to gestational age using the Hadlock (1992) conversion table. Use of a different dating or gestational age conversion method may result in a missed time window for screening for a patient. To assure that the patient and the referring clinician are aware of the correct time window, one of these tools provided should be used:

- **Gestational Age Window for Valid NT Interpretation** - This downloadable table displays the time windows (in both gestational age and mm CRL) for both the blood draws and the NT exam.

- **NT Exam Data and Time Window for Blood Draws Calculator** - This on-line tool uses the NT-CRL and NT Exam Date to calculate the calendar dates of patients' blood draw time windows. The dates can be printed out for both patients and referring clinicians. (See Appendix C.)

Chapter 2: Entering NT Data in the California Prenatal Screening Program

2.1 Methods of Entering NT Data into SIS

NT information must be entered into the Screening Information System (SIS) to be incorporated into risk assessment for prenatal screening. As an NT Practitioner, you can submit data to SIS in three ways. (See Figure 2.1.):

- Logging into SIS and entering the data directly. The patient's 1st Trimester blood specimen must be drawn and submitted to the Program four to seven days before the NT exam. This manual provides detailed instructions for this method of data entry (Section 2.2).
- Recording NT data on the Test Request Form (TRF), which will be carried by the patient to the lab for her 1st or 2nd Trimester blood draw (Section 2.3) and submitted to the Program with the specimen.
- Sending NT data to the referring clinician, who will add the data to a Test Request Form (TRF). **The NT Exam Data Form or the printout from the NT Exam Data and Time Window Calculator** included in Appendices C and D of this manual should be used to communicate data to clinicians (Section 2.4).
- If you are unable to submit data using one of these methods, please call the Prenatal Screening Case Coordinators who oversee and manage case information. While Case Coordinators should not routinely be used as a method of data entry, when a case is time sensitive or no other methods of data entry are available, Case Coordinators can enter data directly into SIS and obtain interpretations. Contact information for Case Coordinators is included in Tables 5.1 and 5.2 of Chapter 5.

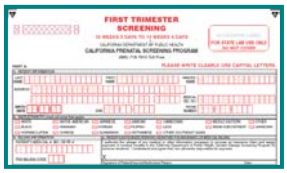
Gestational dating of a pregnancy within the Program is based on the Crown-Rump-Length measured at the time of the NT exam (if available). As such, it is important that NT data be submitted to the Program as soon as possible so that blood draws can be scheduled accordingly.

You may wish to work with your referring clinician base to determine how to schedule NT exams in a way that works best for your practice and your patients. Scheduling the NT exam four to seven days after a patient's blood draw will make it possible to enter NT exam data directly into SIS. Appendix E diagrams different patient flow options and how best to manage NT data depending on when your patients are typically scheduled for NT exams.

Patient tracking and risk assessment will be conducted via the Screening Information System (SIS).

NT Practitioners can submit data in three ways.

Figure 2.1: Methods of Entering NT Data into SIS

		
Enter data directly into SIS for immediate interpretation of results.	Send data to clinicians via fax or mail. Clinicians then incorporate data into patient files and submit it to SIS on Test Request Forms (TRF's).	Enter the data directly onto the Test Request Form (TRF). The data is then submitted to the lab along with the blood specimen.

If data cannot be entered in one of these three ways, please call the Prenatal Screening Coordinator.

The data required for risk assessment is the same regardless of how the information is submitted. In order for the data to be valid, you must include: the patient's identifying Test Request Form (TRF) number or Accession Number, the NT Practitioner Credential Number, NT exam date, Is this a twin pregnancy? (and chorionicity), and valid measurements for both CRL and NT. (See Sections 2.3 and 2.4.)

2.2 Direct Data Entry into SIS

To access SIS, you must complete an e-Course training program, obtain a User ID and password, and sign the NT Practitioner Oath of Confidentiality. You may already be registered as a SIS user for other purposes (PDC Director, Amniocentesis Practitioner, Consultative Sonologist, etc.), but you will not be able to access NT data screens unless you are registered as an NT Practitioner and have completed the training.

If you are a genetic counselor, licensed medical professional (e.g. registered nurse), or qualified medical assistant, you can also become a SIS user and enter NT data into SIS for NT Practitioners. As an NT Data Entry Staff you must complete the same NT Practitioner e-Course referenced above and submit your signed NT Oath of Confidentiality, a Letter of Association signed by a credentialed NT Practitioner, as well as proof of professional licensure or certification before accessing NT data screens.

2.2.1 Logging into SIS

To access SIS, go to the California Department of Public Health at SIS portal page and select **SIS Online Application**. Enter your User ID and password when prompted. (See Figure 2.2.)

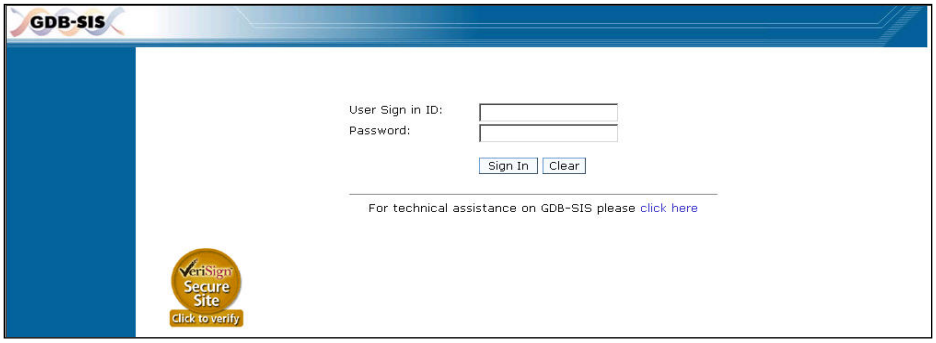


Figure 2.1: SIS Log-In Screen

Access to SIS is restricted to users who have signed an Oath of Confidentiality and have agreed to use confidential information for authorized purposes only. Therefore, you should not share your password with others or utilize browser tools to save passwords on your computer.

Once logged in, you will be directed to the **Select Entity Type** screen. If you have more than one SIS role, you will be given a choice of entity types. You must choose **California NT** or **NT Data Entry Staff** in order to access the **NT Practitioner** screens. (See Figure 2.3.)

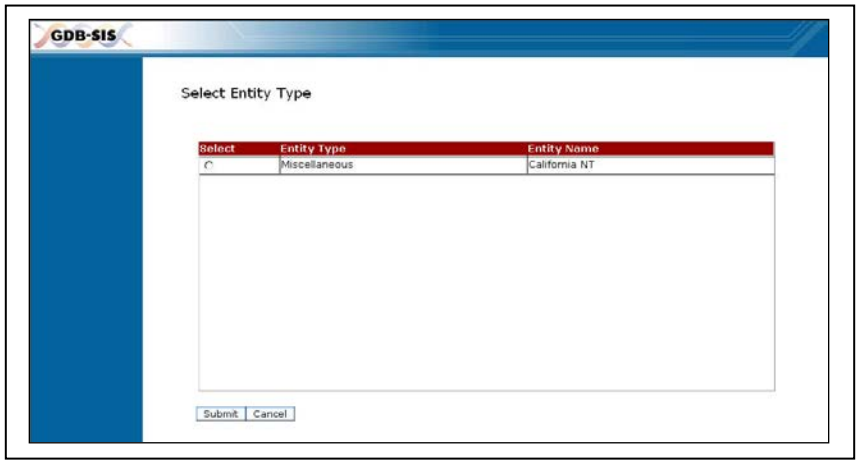


Figure 2.2: Select Entity Type Screen

2.2.2 Searching for a Case

Once you have selected an Entity Type, the **Search for 1st T Specimen** screen will appear. (See Figure 2.4.) Patient records can be accessed using a Test Request Form (TRF) number associated with the patient's blood specimen or the Accession Number that is given to a blood specimen when patient information is entered into SIS. If you do not have either a TRF or Accession Number, you will not be able to enter the data into SIS. Instead, you should use the NT Exam Data and Time Window Calculator (Appendix C) or fill out an NT Exam Data Form (Appendix D) and send a copy to the referring clinician. Both are available online at https://author.cdph.ca.gov/Programs/CFH/DGDS/Pages/ntpractitioners/default.aspx.

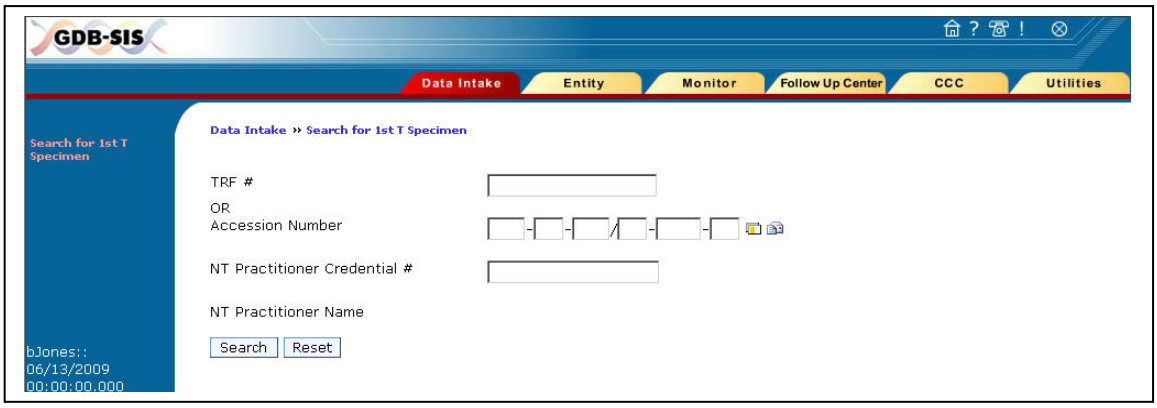


Figure 2.3: Search for 1st T Specimen Screen

You must fill in the NT Practitioner Credential number of the NT Practitioner who conducted the exam. If you are an NT Practitioner, your Credential number will pre-fill this field when you login; if you are an NT Data Entry Staff, this field will be blank when you first log in. The field can be edited so that any NT Practitioner or NT Data Entry Staff who has logged into SIS can enter NT data for multiple NT Practitioners.

It is very important that the correct NT Practitioner Credential number be entered with NT exam data. The Program calculates patient risk assessment based on individual practitioner's medians. Use of the incorrect practitioner's median for case interpretation may result in less accurate risk assessment for your patient.

Once you have entered the TRF number or Accession Number and the correct NT Practitioner Credential number, click Search. If the patient is found in the system, the name, date of birth, and street address of the patient will be automatically filled in. The name of the NT Practitioner will also appear (See Figure 2.5). Please verify that all patient data is correct. If the patient data describes your patient accurately, and if the NT Practitioner name is correct, click **Yes** and proceed to the **Data Entry** screen. If the patient listed on the screen is correct, but the date of birth is inaccurate, please report the correct date of birth to the Case Coordinator. Patient age at term is one factor used to calculate risk; an incorrect date of birth may result in an inaccurate risk assessment.

If the patient listed on the screen is not the patient in your office, or if the NT Practitioner name which appears is incorrect, click **No.** Check the TRF or Accession Number and the NT Practitioner Credential number to verify that you have entered the correct information and click Search again. If you are still unable to find the correct patient in SIS, you will be directed to send data to the referring clinician instead of entering it into SIS. If you think you may have the incorrect Credential ID number, please

check with the Case Coordinator.

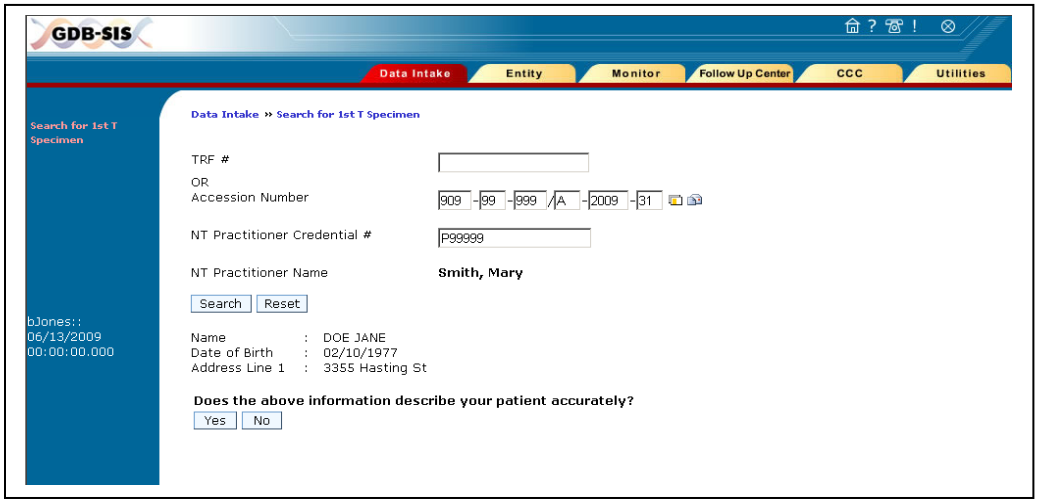


Figure 2.4: Search for 1st T Specimen Screen with Patient Data

Very rarely, SIS may find more than one record matching a TRF number. If this occurs, you must call the Case Coordinator to determine which is the correct record for your patient. The Case Coordinator's telephone number will be provided on the screen. The Case Coordinator may give you an Accession Number to use to access the patient's record.

It is also possible that your patient's record will not yet have been entered into SIS. For example, if her blood has not yet been drawn or if blood was drawn within 2-3 days of her NT exam, your patient's record will not be in SIS. If SIS is unable to locate a record for your patient, you will not be able to enter the data (See Figure 2.6). You must send the NT data to the referring clinician instead of entering it into SIS. If you know that the patient's blood has been drawn, and you would still like to enter data into SIS, you can log into SIS a few days later and search for the patient's TRF number again. Results based on the NT data that you enter will be sent to the referring clinician.

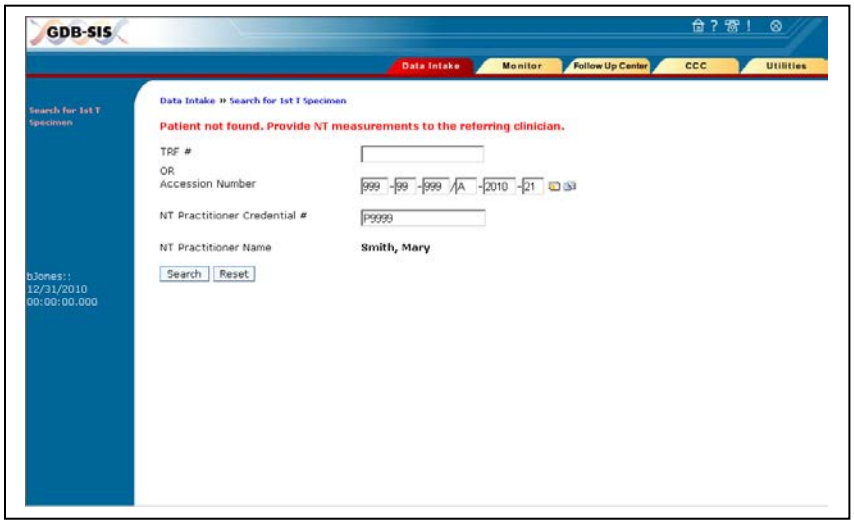


Figure 2.6: SIS Screen with Patient Not Found

2.2.3 Entering Data

Once you have identified the correct patient and NT Practitioner, you will be directed to the **Enter NT Data** screen. The patient's name, date of birth, TRF number, and Accession Number will be pre-filled on the screen, as well as the NT Practitioner Credential ID number and name. You may add a Supervisor Credential Number, Site ID, and Site Name if you wish, although these fields are not required. (See Figure 2.7.) You must enter the NT Exam Date and Crown-Rump-Length (CRL) and NT measurements as well as answer the question 'Is This a Twin Pregnancy?' in order to save the data in SIS. If you indicate that this is a twin pregnancy, you must also enter chorionicity, CRL and NT data for Fetus B.

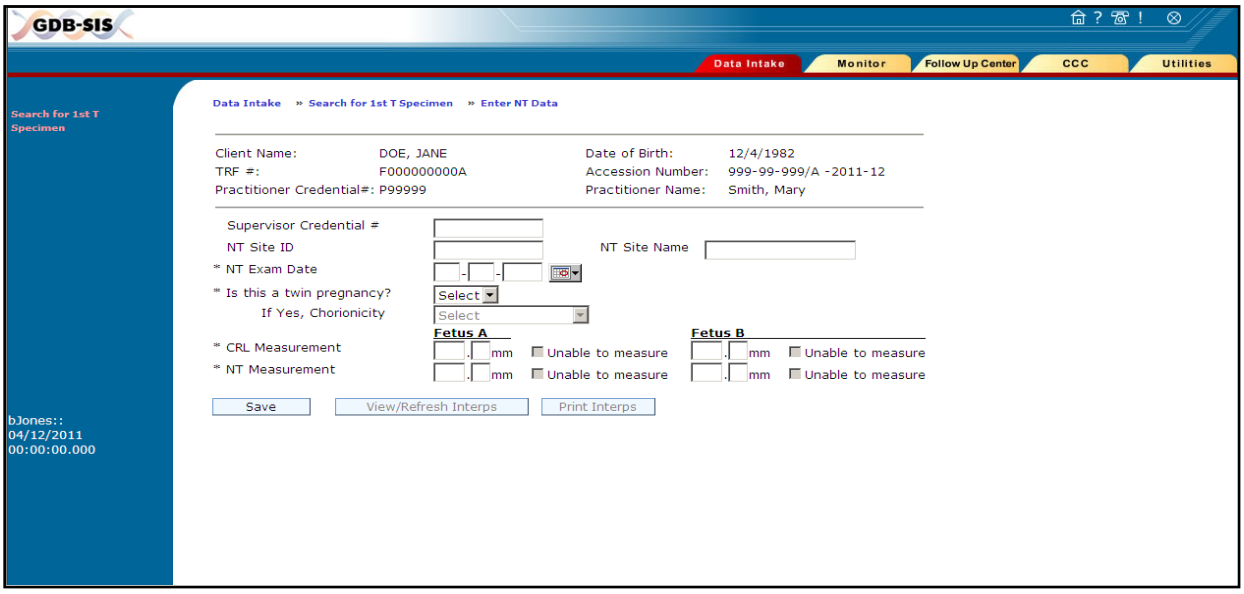


Figure 2.7: Enter NT Data Screen

NT Exam Date

Enter the date on which the NT exam was conducted. If you are not entering the data at the time of the NT exam, be aware that data cannot be added to the case in SIS after the pregnancy reaches a gestational age of 15 weeks 2 days. If you are entering data for a pregnancy beyond this gestational age, please contact the Case Coordinator.

Is This a Twin Pregnancy?

Use the drop-down menu to select **Yes** or **No**. If you have answered **Yes,** you must also indicate if the twins are monochorionic or dichorionic or if the chorionicity cannot be determined. If this is a twin pregnancy, "Unable to Measure" boxes will be activated for both Fetus A and Fetus B. If there is evidence of a fetal demise (resulting in either a twin or singleton pregnancy), report this to the referring clinician or the Case Coordinator. The pregnancy may not be screenable. (See Section 4.3 for more information on fetal demise.)

CRL and NT Measurements

Both the CRL and NT measurement are required fields. If you have indicated that this is a twin pregnancy, you must provide CRL and NT data for both Fetus A and Fetus B. You may indicate "Unable to Measure" for the CRL and/or NT for one of the two fetuses, but complete numeric data (both CRL and NT) must be present for at least one fetus in order for the data to be valid.

Valid CRL Measurements

The valid CRL range for an NT exam for use in risk assessment is **44.6 – 84.5 mm**. This range corresponds to a gestational age range of 11 weeks, 2 days through 14 weeks, 2 days (Hadlock 1992). The Program uses this gestational dating for the pregnancy as well, so blood draws for the purposes of screening should be scheduled accordingly (see Section 1.4). For twin pregnancies, the larger CRL is used for gestational dating.

If you measure a CRL outside of the valid range, SIS will give you an error message that prompts you to take the action shown in Table 2.1:

Table 2.1: CRL Error Messages

CRL	Action
CRL <9.5 mm	Verify data entry. Have patient reschedule NT exam within valid gestational age window.
CRL 9.5 – 44.5 mm	Have patient reschedule NT exam and send current dating information to the referring clinician. **NOTE: The screening result for a case with a large (≥3.0 mm) NT measurement will be *Large NT: Screen Positive* even in this CRL range. Call the Case Coordinator to report the NT data. Your patient is eligible for follow-up services at this time.**
CRL >84.5 mm	Use BPD to calculate gestational age and send dating information to referring clinician for use with 2nd trimester screening.

Valid NT Measurements

The valid range for NT measurements is 0.1–20.0 mm. If you measure an NT larger than 20.0 mm, call the Case Coordinator who will note the actual NT measurement in the patient's record.

2.2.4 Saving Data

Once all required data has been entered, you must click **Save**. You will be prompted to review the data once more before it is saved. Once you click **Yes**, the data is saved and you will not be able to make changes to the screen. (See Figure 2.8.)

Table 2.2 outlines some of the issues you may encounter while working with SIS. In some situations, it is appropriate to call the Case Coordinator who has access to complete case data and may be able to assist you.

Table 2.2: SIS Messages and Status Indicators

SIS Message or Status	Reason/Action
SIS search screen returns "Case not found. Send information to referring clinician."	Patient information has not yet been entered into SIS. Send NT data to the referring clinician.
SIS search screen returns "Multiple matches found. Contact the Case Coordinator at (###) ###-####."	If a TRF number has been assigned to more than one patient, call the Coordinator. The Coordinator may be able to identify the correct patient and give you a unique Accession Number to use on the search screen.
SIS search screen returns a name, date of birth, and address, but the description does not match your patient.	Check the TRF number to ensure that you entered the number correctly. If this is not your patient, click **No** to clear the screen. Send NT exam data to the referring clinician. If this is your patient, but the date of birth is incorrect, contact the Coordinator to update the patient's information.
When you try to save data, SIS screen returns "Based on the CRL, the gestational age today is greater than 15 weeks 2 days. Please send the NT data to the referring clinician or Case Coordinator."	SIS will accept NT data for cases until the pregnancy reaches a gestational age of 15 weeks 2 days. If you are entering NT data after this point, send the data to the referring clinician or Case Coordinator.
When you try to save data on a twin pregnancy, SIS screen returns "Please enter NT and CRL measurements for at least one fetus."	At least one fetus must have complete numeric data (both CRL and NT) in order for the data to be used for risk assessment. The patient may need to be rescheduled for another NT exam during the time window to obtain both measurements.
SIS returns "NT data has already been entered for this case. Please call Case Coordinator at (###) ### ####."	NT data can be entered only once per pregnancy by an NT Practitioner. If another NT Practitioner has already seen this patient and submitted NT data or the data has been updated by a Case Coordinator, you will not be able to access the case. If there is any question about the case, please call the Case Coordinator.
NT data is already filled in, and SIS screen is in read-only mode.	Once you save NT data, you cannot change or re-enter data. If you find that you have made an error and need to correct the data, you must call the Case Coordinator.

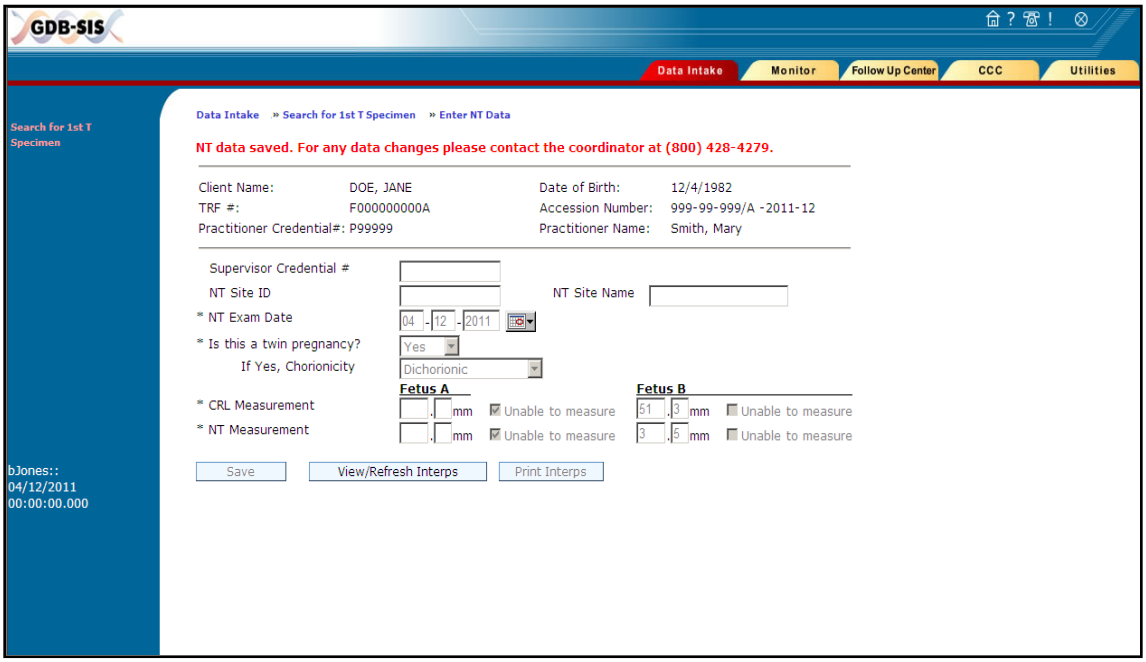


Figure 2.8: NT Data Saved Screen

Periodically, you will not be able to access cases in SIS to enter data directly. This may be because a patient's record has not yet been created in SIS or because SIS cannot identify a record based only on the Test Request Form (TRF) or Accession Number. If this is the case, write the data on the TRF (if provided) or send the data to the referring clinician on one of the Program's NT data forms.

If you know that your patient has recently had her blood drawn, and you would still like to enter data into SIS, you may wait a few days for your patient's SIS record to be created and then enter her NT exam data into SIS. The screening result, based on the NT data you enter, will be sent to the referring clinician.

NOTE: Cases with an NT measurement of 3.0 mm or greater are given a "***Large NT Screen Positive***" result and are eligible for follow-up services. If you measure an NT of 3.0 mm or greater and are not immediately entering data into SIS, please call the case coordinator or referring clinician so that follow-up services can be made available to the patient as soon as possible.

SIS also limits access to cases for which NT measurements have already been entered. If data has been entered by another NT Practitioner or by the Case Coordinator, you will be unable to access the case. If you have previously saved NT data to a case, you will be able to view and print the data through SIS, but you will be unable to make changes to the screen. Please contact the Case Coordinator if you believe data has been erroneously entered into a case.

2.3 Data Entry Using the Test Request Form (TRF)

NT data may be submitted to the Program via the TRF for entry into SIS. (See Figure 2.9.) The TRF is sent to the Program with the blood specimen, and NT data is entered into SIS at the lab.

If the patient brings the TRF to the NT exam, confirm that the patient's name, date of birth and address, and the referring clinician information are correctly entered on the form. Enter the NT data on the TRF and return it to the patient. The patient will bring the TRF to the facility where she has her blood drawn. The facility will submit the TRF with the blood specimen.

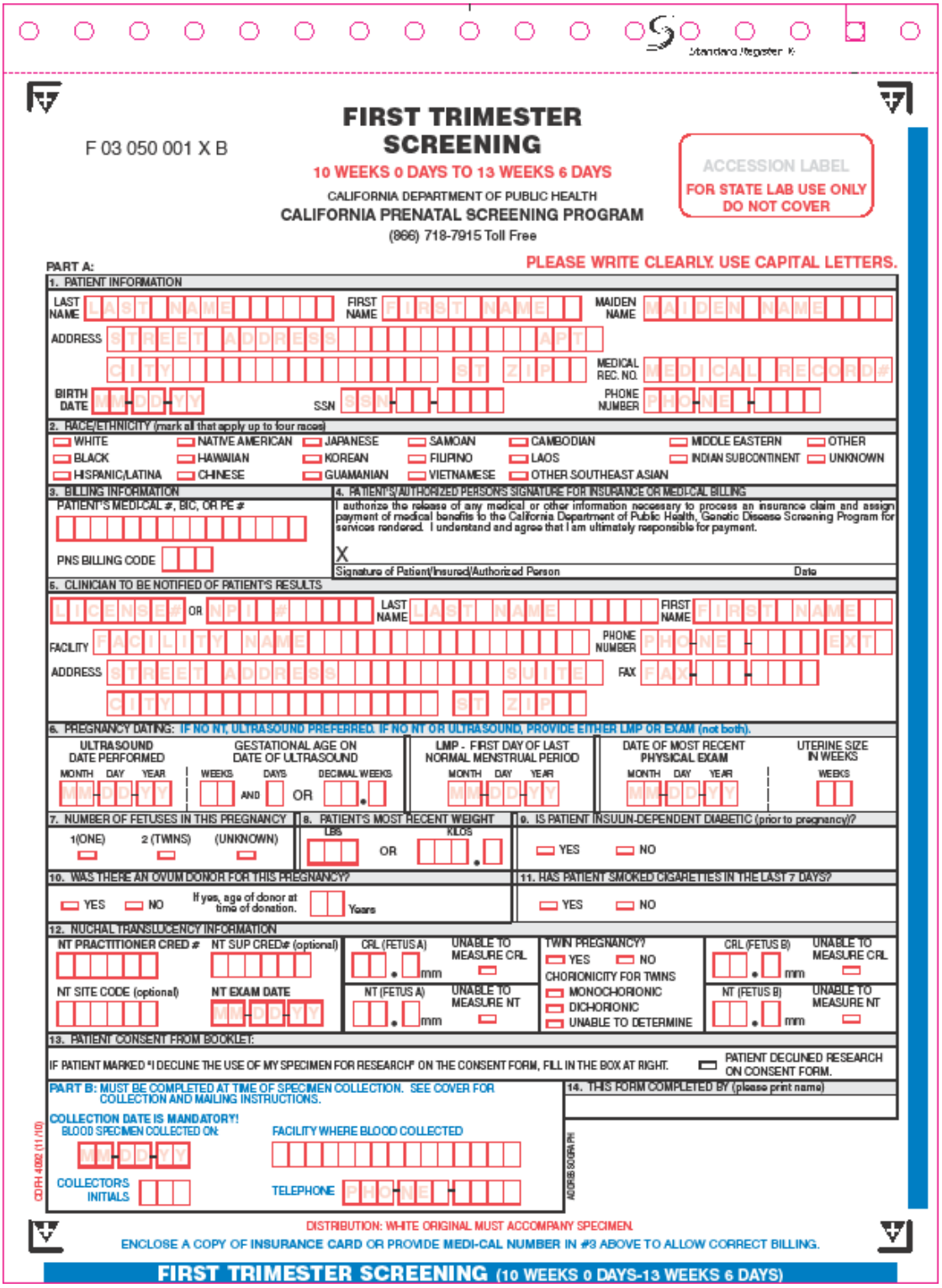


Figure 2.9: First Trimester Test Request Form (TRF)

You must fill out the following fields in order for the NT data to be valid: NT Practitioner Credential ID number, NT Exam Date, Twin Pregnancy? (and chorionicity), and CRL and NT measurement fields.

NT Credential ID Number

The Credential ID number is the number provided to you by FMF or NTQR. If you are credentialed by more than one agency, you may use either number. **It is very important that the correct NT Practitioner Credential number be entered with NT exam data. The Program calculates risk assessment based on individual practitioner's medians. Use of the incorrect practitioner's median for case interpretation may result in less accurate risk assessment for your patient.**

NT Exam Date

Enter the date on which the NT exam was conducted.

Twin Pregnancy?

You must answer the twin pregnancy question. If you answer **Yes,** you must also indicate if the twins are monochorionic or dichorionic or if the chorionicity cannot be determined. If there is evidence of a fetal demise in a twin pregnancy (resulting in either a twin or singleton pregnancy), report this to the referring clinician or the Case Coordinator. The pregnancy may not be screenable. (See Section 4.3 for more information on fetal demise.)

If the pregnancy has three or more viable fetuses, screening blood tests are not valid. The pregnancy is not screenable. Report your NT exam findings to the Case Coordinator and referring clinician, but do not enter them on the TRF.

CRL and NT Measurements

Crown-Rump Length (CRL) and NT measurement must be submitted in millimeters (mm) with no more than one decimal place, e.g. CRL of 59.8 mm or an NT of 1.7 mm. For twin pregnancies, you must provide CRL and NT data for both Fetus A and Fetus B. You may indicate "Unable to Measure" for the CRL and/or NT for one of the two fetuses, but complete numeric data (both CRL and NT) must be present for at least one fetus in order for the data to be valid.

Valid CRL Measurements

The valid CRL range for NT data for use in risk assessment is **44.6 – 84.5 mm**. This range corresponds to a gestational age range of 11 weeks, 2 days through 14 weeks, 2 days (Hadlock 1992). The Program uses this gestational dating for the pregnancy as well, so blood draws for the purposes of screening should be scheduled accordingly. (See Section 1.4) For twin pregnancies, the larger CRL is used for gestational dating.

If the CRL measures **less than 44.6 mm**, enter the NT and CRL measurements on the TRF. This NT exam is not valid for risk assessment, except in the case of a Large (≥ 3.0 mm) NT. The CRL measurement will be used for gestational dating, but the patient should be rescheduled for another NT exam within the appropriate gestational age window. If the CRL measures between 9.5 mm and 44.5 mm, and the NT is greater than or equal to 3.0 mm, the case is ***Large NT: Screen Positive***. If this occurs, please contact the Case Coordinator.

If the CRL measures **more than 84.5 mm**, use the biparietal diameter (BPD) for gestational dating and record this under Section 6: Pregnancy Dating as an ultrasound-based gestational age.

Valid NT Measurements

NT measurements must be entered in millimeters (mm) with no more than one decimal place.

2.4 Transferring Data to the Referring Clinician who will submit it on a TRF

If your patient does not bring the TRF to the NT exam, please send your NT exam results to the referring clinician. NT data will be transferred to the TRF by the referring clinician's office and submitted to the Program on the TRF.

It is important to use one of the Program's standardized forms for reporting NT data even when you provide a more detailed ultrasound report to the referring clinician. The forms utilize the same format and measurement units as the TRF and SIS data entry screens. (See Figure 2.9.) Using the forms can help prevent data transcription errors that can affect your patient's results.

NT Exam Data and Time Window for Blood Draws Calculator – This form can be accessed at NT Calculator (See Figure 2.10 or Appendix C.) The calculator validates the NT exam data as it is entered, and provides a printout of the NT data and the time window for blood draws. A printout of the information can be given both to your patient and to the referring clinician.

NT Exam Data Form - This form is printed as Appendix D.

With either form, the required fields include: Patient's Name and Date of Birth, NT Practitioner Credential ID number, NT Exam Date, Twin Pregnancy? (and chorionicity), and CRL and NT measurements. All data fields must be valid according to the rules outlined above. (See Section 2.3.)

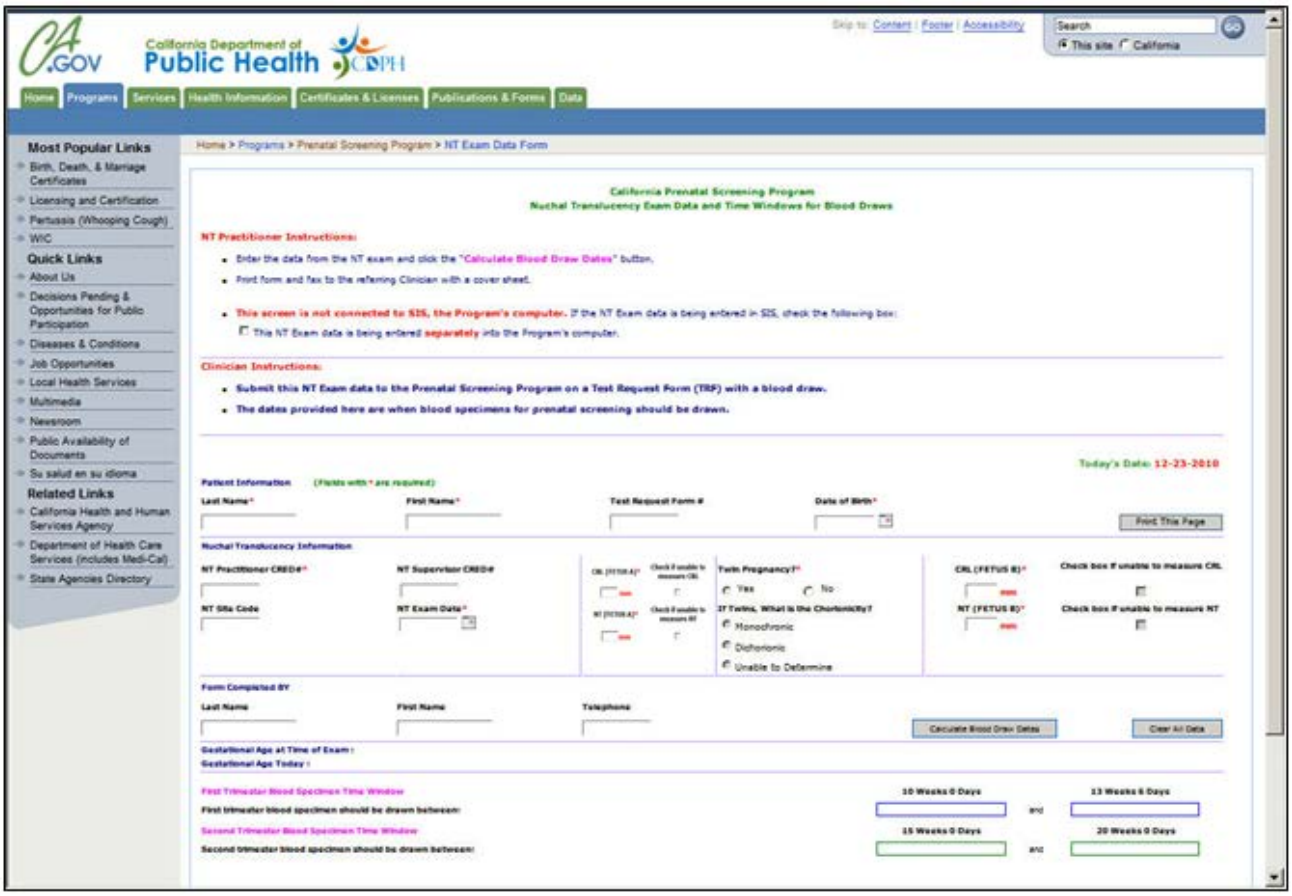


Figure 2.10: NT Data and Time Window for Blood Draws Calculator Screen

2.5 Frequently Asked Questions

An NT Practitioner from our office entered and saved NT data for a case. Can I access the case and view the interpretation?

You will be able to access the case and view the interpretation as long as you have the Credential number for the NT Practitioner who conducted the exam. The screen will be in read-only mode, and you will not be able to edit the data. If you find that there is an error in the data that needs to be changed, you must call the Case Coordinator. Note that if the Case Coordinator enters and saves NT data for a case, you will no longer be able to access the case and view the interpretation.

What do I do if I click Save and then realize that I have entered the data incorrectly?

SIS asks you to check the data before saving because once the data is saved, you will not be able to edit the screen. If you do discover an error after saving, you must call the Case Coordinator to make changes.

What do I do if I cannot get in touch with the Case Coordinator?

There are multiple Case Coordinators covering each region of the State, so you should always be able to contact a Case Coordinator during office hours. In the unusual event that you cannot find a Case Coordinator, you can contact the Genetic Disease Screening Program. Contact information is included in Chapter 5 of this manual.

Why are patients who are not within the valid gestational age range for an NT exam being scheduled?

Until an NT exam is done, gestational dating may be based on ultrasound, last menstrual period (LMP), or physical exam. These methods are less accurate than a CRL measurement and may result in the patient being sent for NT exams prematurely or after the window for an NT exam is closed. CRL dating takes precedence in SIS; once a CRL measurement is entered, the gestational age of the fetus is updated. This may change the gestational age at the time blood was drawn as well and may result in an interpretation of *Too Early* or *Too Late* for the blood specimen. When this happens, Coordinators will notify the clinician on record so that an attempt to re-draw blood within the appropriate screening window can be made.

My patient had her blood drawn yesterday. Why can't I find her TRF number in SIS?

It typically takes 1-2 working days for a specimen to reach the lab, and an additional 1-2 days before the information from the TRF is entered into SIS. You should be able to find your patient in SIS within 3-4 days of the blood draw. The analytical values for the blood test may not yet be available, but you will be able to enter the NT data and save it. If the NT measurement is 3.0 mm or greater, the patient may be eligible for special follow-up services. If you have measured an NT of 3.0 mm or greater, and you are unable to immediately enter the data into SIS, please call the Case Coordinator or referring clinician to notify them of the large NT.

My exam indicates that there was a fetal demise but that there is still a viable remaining fetus. Should I submit the exam results for the remaining fetus?

This depends on the age of the demised fetus. If the demise was before 8 weeks (CRL < 16.0 mm), your patient can obtain 2nd Trimester screening (Quad + NT). Report the NT exam data as usual and report the demise to the referring clinician or the Case Coordinator. If there has been a fetal demise at or after 8 weeks (CRL ≥ 16.0 mm), interpretation of the blood analysis will not be valid for this pregnancy. The exception is when the NT for a remaining viable fetus is ≥ 3.0 mm. The screening result in this case will be ***Large NT: Screen Positive*** even though blood analysis results are invalid. Contact the office of the referring clinician or the Case Coordinator to report the findings of your exam. See Section 4.3 for more information.

Once I have entered the NT data into SIS, should I also send the information to the referring clinician and the Coordinator?

You only need to report NT data to SIS once. If you have submitted the data to SIS, either by direct input, via the TRF or by sending it to the referring clinician, you do not need to report it to the Case Coordinator. However, you should still send an ultrasound report to the referring clinician with any findings that were not entered into SIS.

My patient had her NT exam and blood drawn on the same day, but SIS shows that the specimen was Too Late. How is this possible?

The gestational age window for the NT exam and the 1st Trimester blood draw overlap, but are not the same. A 1st Trimester blood specimen can be drawn between 10 weeks 0 days and 13 weeks 6 days, but the NT exam can be conducted between 11 weeks 2 days and 14 weeks 2 days. The gestational age window during which both the NT exam and 1st Trimester blood draw can be done is 11 weeks 2 days

(44.6 mm CRL) and 13 weeks 6 days (79.4 mm CRL). For more information, please refer to Figure 1.1 and Appendix B.

My patient has an NT measurement of 3.0mm or more. Is she Screen Positive if she is having her blood drawn on the same day? Can she be seen for follow-up?

Until a patient's blood specimen has been received by the laboratory and entered into SIS, there is no record of this pregnancy in the Program's system. NT data cannot be entered into SIS. The patient cannot be given a screening result or referred for follow-up within the Program until analytical results are provided by the lab. If you measure an NT of 3.0 mm or greater, and you are unable to immediately enter the data into SIS, please call the Case Coordinator or referring clinician to notify them of the large NT. Once screening results are available, she may be referred to a Prenatal Diagnostic Center for follow-up services at no additional cost. If your patient wishes to obtain follow-up services immediately, she may be referred outside of the Program and she or her insurance company will be billed.

Chapter 3: Viewing and Printing Interpretations in SIS

3.1 Introduction

Once NT data is entered into SIS, the information is combined with available blood analysis to produce a risk assessment. SIS reports a first trimester preliminary numeric risk for Down syndrome and Trisomy 18 and a screening result. Patients receiving a first trimester preliminary ***Screen Negative*** result may submit a second trimester blood specimen to obtain Sequential Integrated Screening and a refined risk assessment based on the two blood specimens and NT measurement.

Risks higher than 1 in 100 for Down syndrome, and risks higher than 1 in 150 for Trisomy 18 are ***Screen Positive***. Patients receiving ***Screen Positive*** results are offered follow-up services including genetic counseling and either chorionic villus sampling (CVS) or noninvasive prenatal testing (NIPT) at no additional cost in the first trimester, or the option of waiting until the second trimester for follow-up services which include an ultrasound and either amniocentesis or NIPT, or having further blood testing and refined risk assessment in the second trimester.

For cases with an NT measurement ≥ 3.0 mm, the screening result is ***Large NT: Screen Positive***, regardless of the results of blood analysis. The ***Large NT: Screen Positive*** result indicates a greater than 1 in 5 risk for chromosomal abnormalities or cardiac defects. Patients receiving a ***Large NT: Screen Positive*** result are offered all of the follow-up services available to ***Screen Positive*** patients.

3.2 Viewing Interpretations

Once you have entered and saved NT data, you can view the current interpretation of the case by clicking **View/Refresh Interps** on the saved data screen. (See Figure 3.1.)

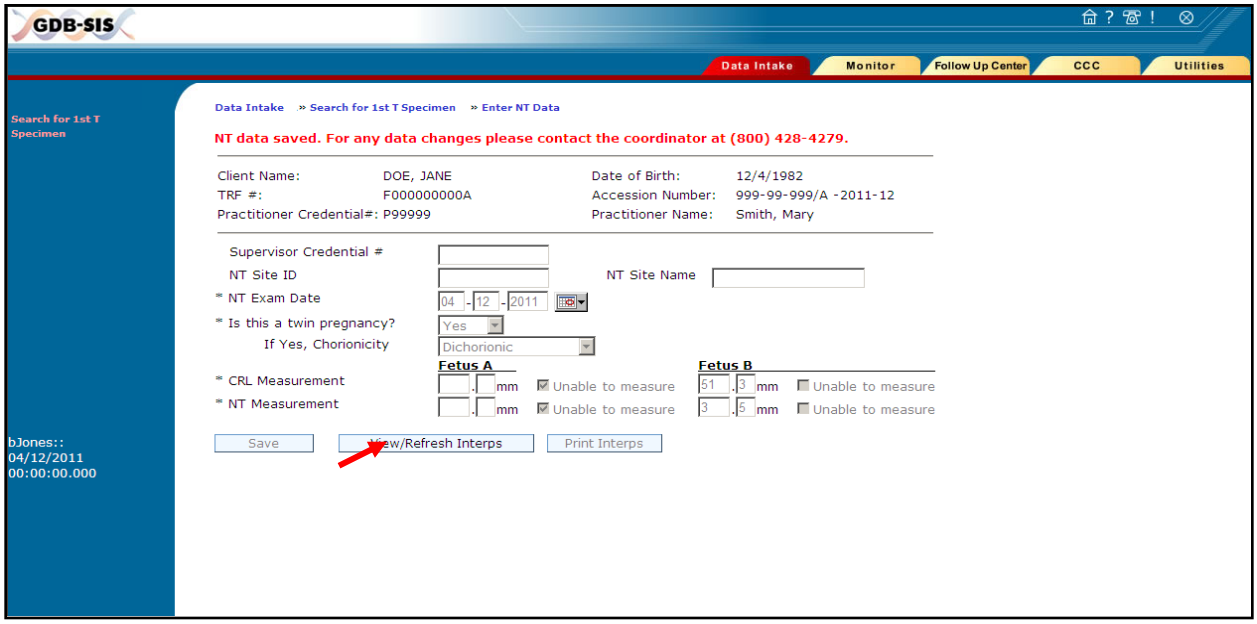


Figure 3.1: Saved Data Screen

Screen Negative

If the case is ***Screen Negative***, you may view the interpretation and communicate the results to your patient immediately. The interpretation includes both the screening result (***Screen Negative/Screen Positive***) and the numerical risk assessment for Down syndrome and Trisomy 18. (See Figure 3.2.)

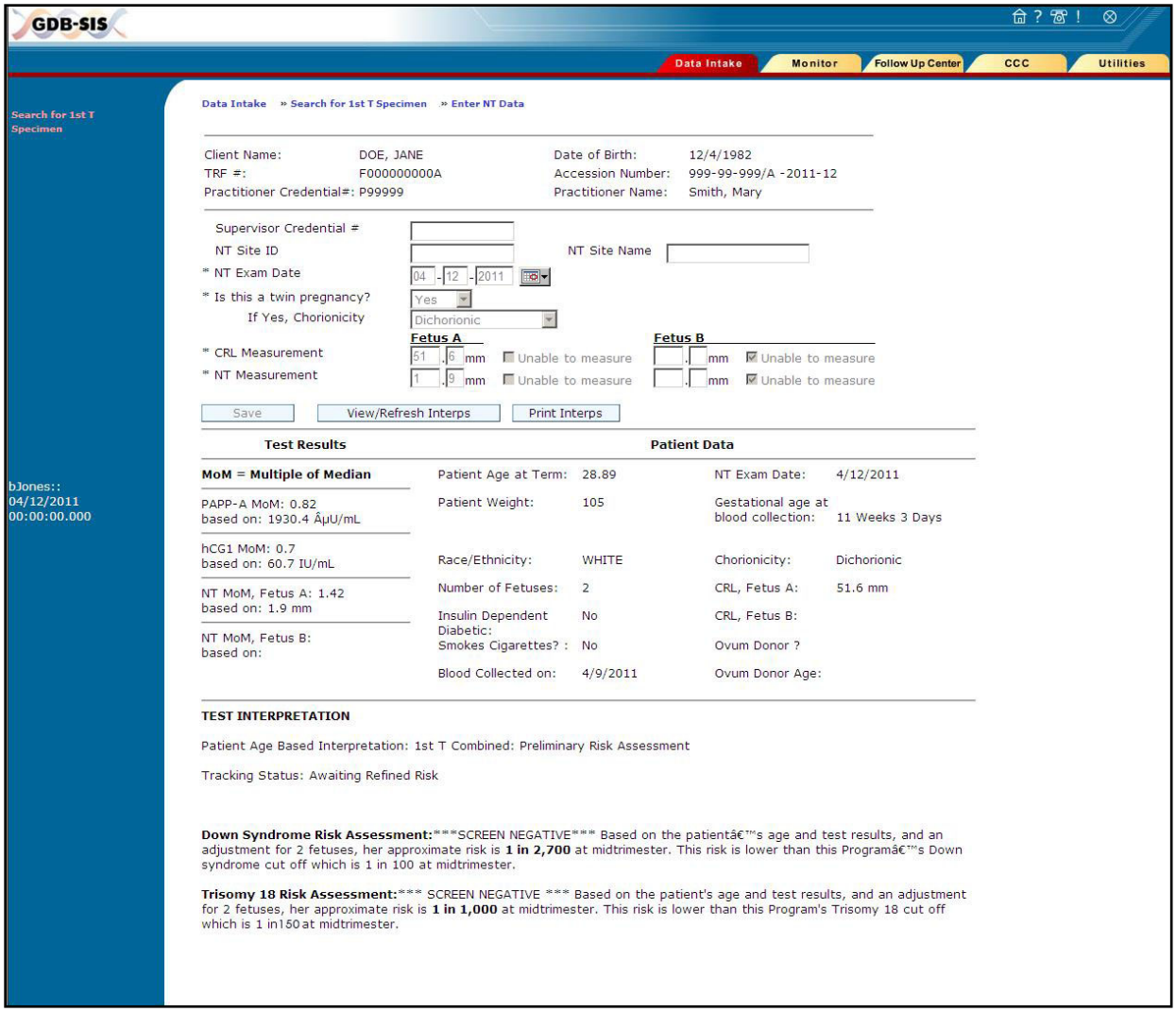


Figure 3.2: Interpretation Display

NOTE: ***Screen Negative*** patients have the option of participating in second trimester blood screening for a refined risk assessment.

3.2.1 Insufficient Information or Screen *Positive*

If the case is ***Screen Positive*** or ***Large NT: Screen Positive***, or if it is missing information necessary to perform an interpretation, you must speak with the Case Coordinator and verify interpretation factors before obtaining the interpretation. (See Figure 3.3.)

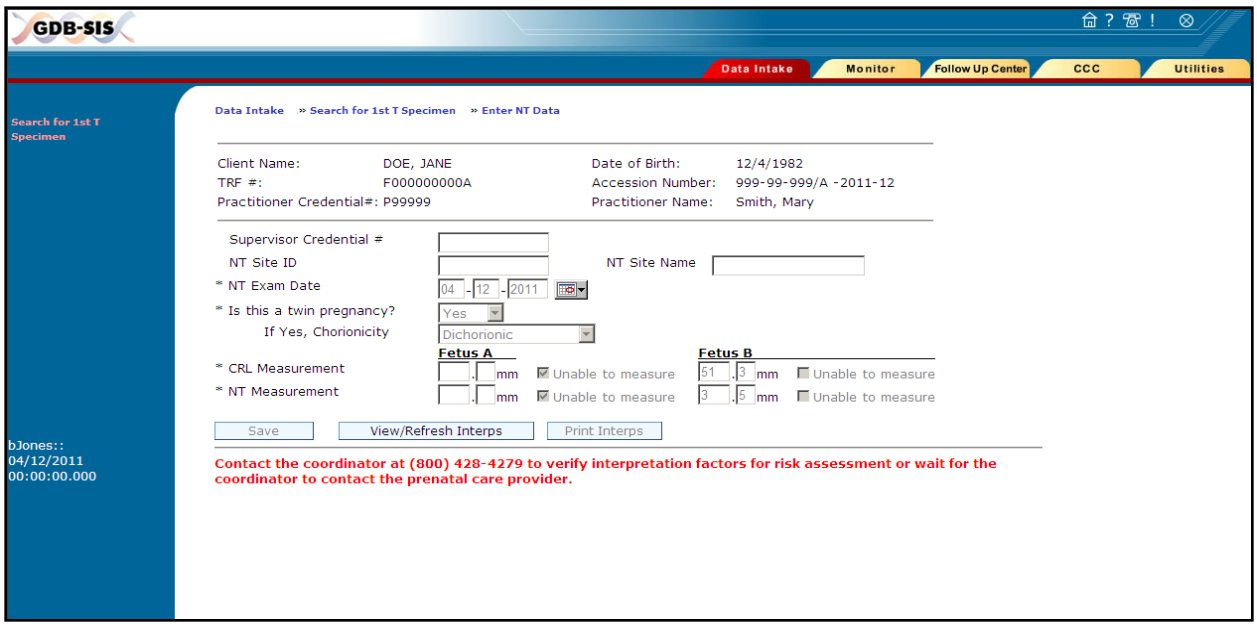


Figure 3.3: Notification to Contact Case Coordinator

If you see the message displayed in Figure 3.3, you have the option of not following the case through; the Case Coordinator will contact the clinician, who will communicate results to the patient.

If you do wish to obtain the interpretation, call the Case Coordinator at the number provided. He or she will have you obtain or verify some of the patient information critical to the case interpretation. Case information must include the patient's date of birth, blood collection date, most recent weight, insulin-dependent diabetes status, smoking status, and race/ethnicity. For the purpose of case interpretation, race/ethnicity categories are defined as White, Black, Chinese, Korean, Japanese, Vietnamese, Laotian, Filipino, Other Southeast Asian, Samoan, Guamanian, Hawaiian, Indian, Native American, Middle Eastern, Hispanic, Other, or Unknown. A patient may select one or more race/ethnicity categories.

If all interpretation factors can be confirmed, the Case Coordinator will reinterpret the case. You will then be able to view the interpretation by clicking ***View/Refresh Interps.*** (See Figure 3.4.) If interpretation factors cannot be confirmed, the Case Coordinator will follow up with the referring clinician and you will not be able to view the interpretation.

Screen Positive and ***Large NT: Screen Positive*** results must be presented to patients in conjunction with the follow-up options available to them. When ***Screen Positive*** and ***Large NT: Screen Positive*** results are printed, SIS also generates a page detailing patient options for follow-up care. This page must be given to the patient. (See sample page in Appendix A.) For more information on how to communicate results to your patient, and for information on follow-up options, please see Chapter 4.

As with ***Screen Negative*** patients, all ***Screen Positive*** patients have the option of participating in second trimester blood screening for a refined risk assessment and to be screened for neural tube defects and Smith-Lemli-Opitz syndrome (SCD).

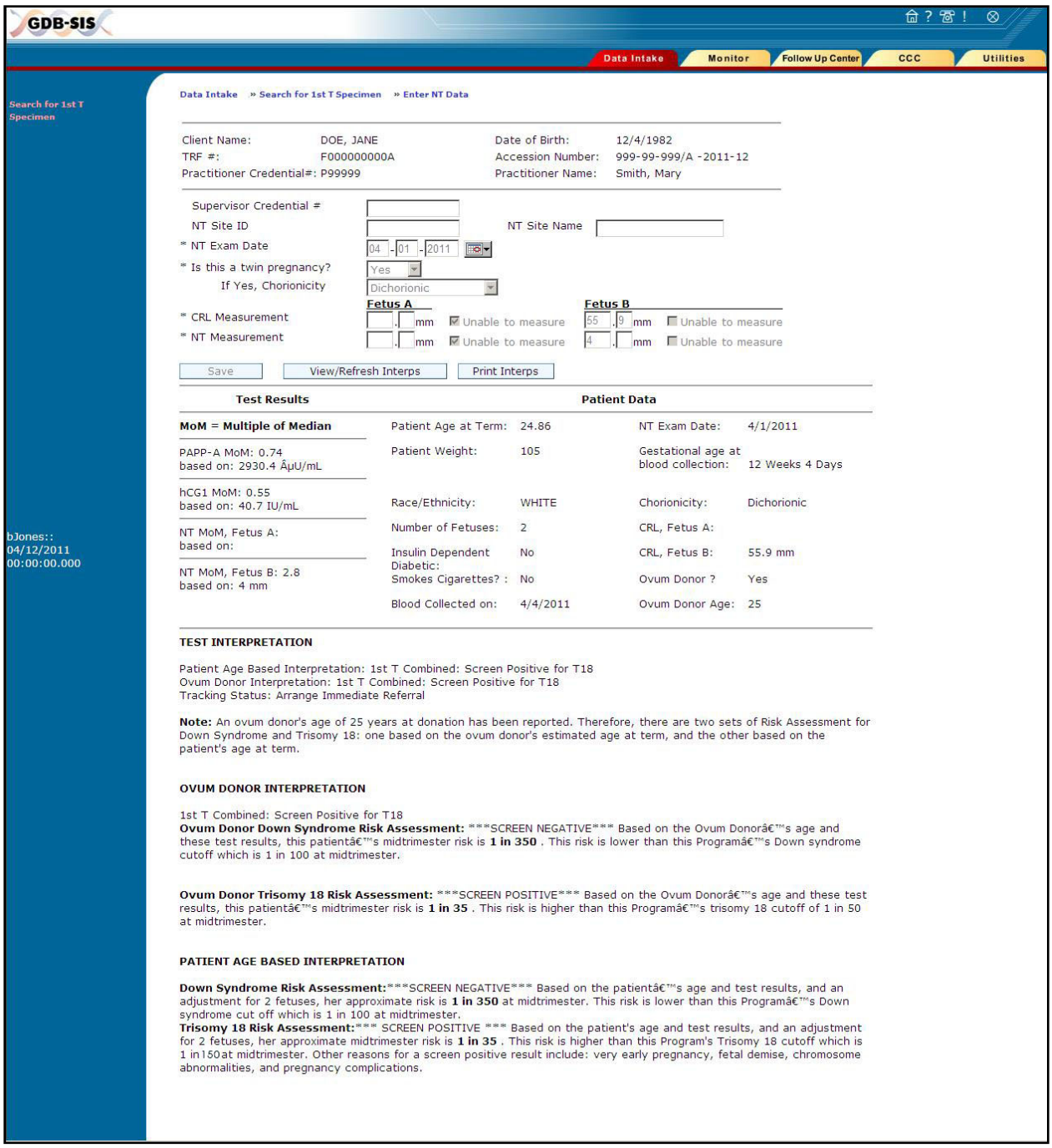


Figure 3.4: *Screen Positive* Interpretation Screen

3.2.2 Other Potential Scenarios

Depending on the status of the case, one of several other messages related to case interpretation may appear on the SIS screen. These messages are listed in Table 3.1.

Table 3.1: Other SIS Messages Related to Interpretation

Message	Case Status	Required Action
Laboratory results not yet available. Tracking Status: Pending; waiting for test results.	NT information is valid, but results of blood analysis are not yet available.	Results will not be immediately available to patient. Referring clinician will follow up with results.
Tracking Status: Tell Clinician ***Too Early*** (or ***Too Late***)	NT information is valid, but blood specimen was collected outside of the valid gestational age range for blood testing. Case Coordinator will follow up.	Results will not be immediately available to patient. Case Coordinator will follow up with referring clinician.

3.3 Printing Instructions

Clicking the **Print Interp** button will print whatever case information is available. This includes ***Screen Positive*** and ***Screen Negative*** results as well as case status in situations in which case interpretation has not been conducted. SIS will also print a follow-up options page for all cases with a ***Screen Positive*** or ***Large NT: Screen Positive*** interpretation. This options page must be given to the patient. (See sample page in Appendix A.)

3.4 Frequently Asked Questions

I have looked at the Screen Negative results for my patient. Some of the patient data looks incorrect. Should I have this data corrected? Will it affect the interpretation?

Interpretation of results is based on a number of factors, including your patient's age, gestational age, race, and most recent weight. If the information listed on the interpretation is not accurate, please contact the Case Coordinator. Changing the factors may change the case interpretation, and the Case Coordinator will be able to reinterpret the case immediately.

My patient says that she had blood drawn when her physician told her to. How can it be too early (or too late)?

Until an NT exam is done, gestational dating may be based on ultrasound, last menstrual period (LMP), or physical exam. These methods are less accurate than a CRL measurement and may result in the patient being sent for her blood draw prematurely or after the window for the first trimester blood specimen is closed. Once a CRL measurement is entered, the gestational age of the fetus is updated. This may change the gestational age at the time that blood was drawn as well and may result in a ***Too Early*** or ***Too Late*** result for the blood specimen. Clinicians can work with patients to get another blood specimen within the valid time frame. If it is too late to redraw a valid first trimester blood specimen, NT information can be used in conjunction with a

second trimester blood specimen for Quad + NT screening. The gestational age window for a second trimester blood draw starts at 15 weeks 0 days.

My patient would like to get her results as soon as possible, but the results of blood analysis are not yet in SIS. How soon can she see her results?

Blood analysis results are available in SIS a few days after the specimen is entered into SIS which is usually within a week of the specimen collection date. Your patient should contact her clinician directly.

Chapter 4: Discussing NT Exam Findings

4.1 Disclosure of Results

As an NT Practitioner, you are responsible for informing ***Screen Positive*** and ***Large NT: Screen Positive*** patients of follow-up options that are available to them. A page detailing the patient's options for follow-up will print with the Screening Information System (SIS) results. A copy of the options page is provided in Appendix A and is discussed below. You must review the options with the patient and provide a copy of this page to her.

In all situations other than ***Screen Negative***, Case Coordinators contact the referring clinician's office to verify case information and facilitate redraws or referrals for follow-up care as needed.

If you are an NT Practitioner working at a state-approved Prenatal Diagnosis Center (PDC), you may offer same-day follow-up to ***Screen Positive*** and ***Large NT: Screen Positive*** patients. However, before follow-up services can be provided, the patients must meet with an on-site, state-approved Genetic Counselor to discuss risks and benefits of available follow-up testing options.

4.1.1 Option One

If the PDC offers chorionic villus sampling (CVS) by a state-approved CVS Practitioner, the center can perform either a transcervical or transabdominal CVS between 10 and 14 weeks. Patients with a ***Large NT: Screen Positive*** result may also have an additional first trimester fetal ultrasound.

4.1.2 Option Two

If the PDC does not offer chorionic villus sampling (CVS), the center can still provide genetic counseling. The patient will then be referred to another state-approved PDC if she wants a CVS and/or a first trimester ultrasound (in the case of ***Large NT: Screen Positive*** results).

4.1.3 Option Three

The patient may wait until the second trimester (15–24 weeks) for an ultrasound and amniocentesis at a state-approved PDC.

NOTE: If the patient goes to a state-approved PDC for any of the above-authorized follow-up services, there is no charge to the patient or her insurance company.

4.1.4 Option Four

The patient may seek diagnostic follow-up on her own, and she or her insurance company will be billed.

4.1.5 Option Five

The patient can have a second trimester blood screening test between 15 and 20 weeks for a refined risk assessment for Down syndrome and Trisomy 18. Second trimester screening also includes risk assessment for neural tube defects, abdominal wall defects, and Smith-Lemli-Opitz syndrome.

If the result of Sequential Integrated (first and second trimester) Screening is ***Screen Positive***, the patient will be offered follow-up, at no charge, at a state-approved PDC.

If the result of Sequential Integrated Screening is ***Screen Negative***, no additional follow-up services are authorized.

For ***Large NT: Screen Positive*** cases, the additional blood draw will not change the screening result for chromosomal abnormalities. All follow-up services will still be available, at no additional charge.

4.1.6 Option Six

The patient can choose not to have any follow-up at all.

4.2 Notification of Patient Follow-Up Decision

Screen Positive patients who have had an NT exam at a state-approved PDC may obtain same-day follow-up services at the PDC, however the PDC should notify the Case Coordinator of the patient's follow-up decision. If your office does not offer on-site genetic counseling, or if the patient does not wish to schedule same-day services, she should contact her clinician directly regarding the result and her decision about follow-up.

4.3 Communication of Other Potential Findings of the NT Exam

The NT exam may be the patient's first ultrasound and the first time that multiple fetuses are detected. If two fetuses are found you must determine chorionicity or indicate "unable to determine" in order for the case to be interpreted (See Chapter 2). If more than two viable fetuses are found, call the Case Coordinator to have this information entered into the patient's record. The Program cannot interpret a case with more than two viable fetuses.

Fetal demise may affect the interpretation of blood analyte results. If there is evidence of fetal demise (reduction of twins to a singleton, or reduction of triplets to twins) and the non-viable fetus has no measurable CRL, or if the gestational sac is empty, proceed with the exam and report the results for the remaining viable fetus or fetuses as you normally would.

If the non-viable fetus appears to be less than 8 weeks old (CRL < 16.0 mm), proceed with the exam and report the fetal demise and the NT data to the referring clinician and to the Case Coordinator. Inform the patient that she will be unable to obtain 1st Trimester combined risk assessment, but that she should schedule a 2nd Trimester blood draw to obtain Quad + NT screening.

If the non-viable fetus appears to be 8 weeks old or greater (CRL ≥ 16.0 mm), the pregnancy is not screenable. Do not enter data into SIS for this pregnancy. Call the Case Coordinator to report the results of your exam and send the information to the referring clinician in the ultrasound report.

An exception to the fetal demise rules is made if the remaining viable fetus has a Large (≥ 3.0 mm) NT. If you determine that there has been a fetal demise (twins to singleton, or triplets to twins) and a remaining viable fetus has a Large NT, contact the Case Coordinator to report the results of your exam. The case will be ***Large NT: Screen Positive***, and your patient will be eligible to receive follow-up through the Program.

Risk assessment cannot be conducted on any pregnancy in which there has been an elective fetal reduction, regardless of the gestational age at the time of the reduction. Risk assessment also cannot be conducted on any pregnancy with three or more viable fetuses. If your patient has undergone fetal reduction in this pregnancy or if you identify a fetal demise that has reduced triplets (or more) to a singleton or twin pregnancy, do not submit NT data to SIS; instead, call the Case Coordinator so that information on the pregnancy can be entered into SIS. These procedures are summarized in Table 4.1 below.

In addition, large NT measurements, defined as NT measurements greater than or equal to 3.0 mm, are associated with a number of adverse pregnancy outcomes including a greater than 1 in 5 risk of congenital heart defects and chromosomal abnormalities. Cases with an NT measurement ≥ 3.0 mm are ***Large NT: Screen Positive*** unless NT exam was performed when the CRL was more than 84.5 mm. An NT measurement ≥ 3.0 mm should be reported directly to the referring clinician as well as entered in SIS.

NT exams may also identify fetal abnormalities that are outside the scope of the Prenatal Screening Program. SIS does not have the capacity to incorporate this information; recommendations for follow-up, genetic counseling, or further diagnostic exams should be communicated to the referring clinician.

Table 4.1: Screening Procedures When Multiple Fetuses are Detected

If you detect:	NTP should:	Inform patient that:
Twins with no Fetal Demise	Submit NT exam data for a twin pregnancy.	1st and 2nd Trimester screenings are available for this pregnancy (if patient's blood was drawn during the appropriate timeframe). Patient should schedule a 2nd Trimester blood draw to obtain sequential integrated screening.
Fetal Demise at ≥ 8 weeks	Notify Case Coordinator, and send information to the referring clinician.	Prenatal screening based on blood specimens cannot be provided for this pregnancy.*
Fetal Demise at < 8 weeks	Notify Case Coordinator, and send information to the referring clinician.	1st Trimester combined screening cannot be provided. Patient should schedule a 2nd Trimester blood draw to obtain Quad+NT screening.*
An empty gestational sac	Proceed with exam as usual.	1st Trimester combined screening is available for the viable fetus or fetuses (if patient's blood was drawn during the appropriate timeframe). Patient should schedule a 2nd Trimester blood draw to obtain sequential integrated screening.
Elective Fetal Reduction	Notify Case Coordinator, and send information to the referring clinician.	Prenatal screening cannot be provided for pregnancies in which there has been an elective fetal reduction.
Three or more viable fetuses	Notify Case Coordinator, and send information to the referring clinician.	Prenatal screening cannot be provided for pregnancies with three or more viable fetuses.

*In the case of a fetal demise, if the remaining viable fetus has an NT measurement ≥ 3.0 mm, this case will be ***Large NT: Screen Positive***, regardless of when the demise took place. If you encounter this situation, please call the Case Coordinator.

Chapter 5: Program Contact Information

This chapter provides contact information and reference material related to the California Prenatal Screening Program. If you have questions that are not addressed in this manual, please contact GDSP at the numbers shown in Section 5.3 below.

5.1 NT Practitioner Credential Status Issues

If you have questions related to your credential status, or if you are unsure if you have been registered with the Program, please contact NTQR or FMF. For information on becoming a credentialed NT Practitioner, please visit the organizations' websites.

Nuchal Translucency Quality Review
Jean Lea Spitz
(405) 753-6534
NTQRSupport@NTQR.org
www.ntqr.org

OR

Fetal Medical Foundation
Naomi Greene
(818) 395-0611
naomiHG@fetalmedicine.com
www.fetalmedicineusa.com

5.2 Case Coordinator Contact Information

Case Coordinators are assigned to cases based on the location of the referring clinician. SIS will provide the appropriate Case Coordinator Center (CCC) phone number to call under a number of scenarios (See Chapter 2).

Table 5.1 shows CCC numbers and contact information, by county, for your reference. If your patient's clinician is located in Los Angeles County or San Mateo County, use the detailed ZIP code guide in Table 5.2 to identify the Case Coordinator. If you are unable to identify the appropriate CCC, call the Genetic Disease Screening Program (GDSP) Coordinator listed in Section 5.3.

Table 5.1: California Prenatal Screening Program Case Coordination Center Assignments

County	CCC	Toll free Phone Number	Phone Number	FAX Number
Alameda	43	(800) 428-4279	(916) 734-6228	(916) 734-0637
Alpine	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Amador	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Butte	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Calaveras	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Colusa	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Contra Costa	43	(800) 428-4279	(916) 734-6228	(916) 734-0637
Del Norte	41	(800) 559-5616	(916) 734-6551	(916) 734-0637
El Dorado	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Fresno	45	(800) 237-7466	(559) 353-6645	(559) 353-7215
Glenn	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Humboldt	41	(800) 559-5616	(916) 734-6551	(916) 734-0637
Imperial	52	(866) 366-4408	(858) 822-1280	(858) 822-1284
Inyo	51	(877) 224-4373	(714) 456-5994	(877) 757-5437
Kern	45	(800) 237-7466	(559) 353-6645	(559) 353-7215
Kings	45	(800) 237-7466	(559) 353-6645	(559) 353-7215
Lake	41	(800) 559-5616	(916) 734-6551	(916) 734-0637
Lassen	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Los Angeles	47-50	See Table 5.2 - ZIP Code Chart		
Madera	45	(800) 237-7466	(559) 353-6645	(559) 353-7215
Marin	41	(800) 559-5616	(916) 734-6551	(916) 734-0637
Mariposa	45	(800) 237-7466	(559) 353-6645	(559) 353-7215
Mendocino	41	(800) 559-5616	(916) 734-6551	(916) 734-0637
Merced	45	(800) 237-7466	(559) 353-6645	(559) 353-7215
Modoc	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Mono	51	(877) 224-4373	(714) 456-5994	(877) 757-5437
Monterey	44	(877) 871-6467	(916) 734-6078	(916) 734-0625
Napa	41	(800) 559-5616	(916) 734-6551	(916) 734-0637
Nevada	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Orange	51	(877) 224-4373	(714) 456-5994	(877) 757-5437
Placer	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Plumas	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Riverside	52	(866) 366-4409	(858) 822-1281	(858) 822-1285
Sacramento	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
San Benito	44	(877) 871-6467	(916) 734-6078	(916) 734-0625

County	CCC	Toll free Phone		
San Bernardino	51	(877) 224-4373	(714) 456-5994	(877) 757-5437
San Diego	52	(866) 366-4410	(858) 822-1282	(858) 822-1286
San Francisco	41	(800) 559-5616	(916) 734-6551	(916) 734-0637
San Joaquin	43	(800) 428-4279	(916) 734-6228	(916) 734-0637
San Luis Obispo	44	(877) 871-6467	(916) 734-6078	(916) 734-0625
San Mateo	41, 44	See Table 5.2 - ZIP Code Chart		
Santa Barbara	47	(877) 568-9237	(323) 866-6790	(323) 866-6791
Santa Clara	44	(877) 871-6467	(916) 734-6078	(916) 734-0625
Santa Cruz	44	(877) 871-6467	(916) 734-6078	(916) 734-0625
Shasta	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Sierra	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Siskiyou	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Solano	41	(800) 559-5616	(916) 734-6551	(916) 734-0637
Sonoma	41	(800) 559-5616	(916) 734-6551	(916) 734-0637
Stanislaus	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Sutter	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Tehama	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Trinity	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Tulare	45	(800) 237-7466	(559) 353-6645	(559) 353-7215
Tuolumne	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Ventura	47	(877) 568-9237	(323) 866-6790	(323) 866-6791
Yolo	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Yuba	42	(800) 391-8669	(916) 734-6575	(916) 734-0625
Kaiser Permanente				
Northern CA	53		(510) 752-6190	(510) 752-6800
Southern CA	54		(626) 564-3322	(626) 564-3311
State of Nevada - all	42	(800) 391-8669	(916) 734-6575	(916) 734-0625

Table 5.2: ZIP Code Guide for San Mateo and Los Angeles County Case Coordination Center Assignments

CCC 41 – Phone (916) 734-6551 / Toll Free (800) 559-5616 / FAX (916) 734-0637

94005, 94010, 94011, 94013–94015, 94018–94019, 94030, 94037, 94038, 94044, 94066, 94080, 94401–94404

CCC 44 – Phone (916) 734-6078 / Toll Free (877) 871-6467 / FAX (916) 734-0625

94002, 94020, 94021, 94025–94028, 94060–94065, 94070, 94074, 94303

CCC 47 – Phone (323) 866-6790 / Toll Free (877) 568-9237 / FAX (323) 866-6791

90024, 90034, 90035, 90049, 90066, 90073, 90077, 90095, 90213 – 90215, 90265, 90272, 90290 – 90293, 90401 – 90406, 91040, 91042, 91102, 91126, 91301 – 91311, 91316, 91320 – 91322, 91324 – 91326, 91328, 91331, 91332, 91335, 91340 – 91345, 91350, 91351, 91354 – 91356, 91358, 91360 – 91362, 91364, 91367, 91384, 91387, 91390, 91401 – 91406, 91411, 91412, 91423, 91436, 93510, 93532, 93534 – 93539, 93543, 93544, 93550 – 93553, 93563, 93591

CCC 48 – Phone (323) 866-6750 / Toll Free (888) 330-9237 / FAX (323) 866-6755

90004 – 90006, 90010, 90012, 90014 – 90020, 90026 – 90031, 90036, 90038, 90039, 90041, 90042, 90046, 90048, 90057, 90065, 90068, 90069, 90071, 90072, 90089, 90210 – 90212, 91001, 91006, 91007, 91010, 91011, 91016, 91020, 91024, 91030, 91046, 91101, 91103 – 91109, 91123, 91125, 91201 – 91209, 91214, 91225, 91226, 91352, 91501 – 91506, 91601, 91602, 91604 – 91609, 91706, 91747, 91769, 91775, 91776, 91778, 91780, 91793

CCC 49 – Phone (323) 866-6788 / Toll Free (888) 844-9237 / FAX (323) 866-6789

90001 – 90003, 90007, 90008, 90011, 90013, 90021 – 90023, 90025, 90032, 90033, 90037, 90040, 90043 – 90045, 90047, 90056, 90058, 90062 – 90064, 90067, 90230, 90232, 90234, 90245, 90255, 90270, 90301 – 90306, 90308, 90640, 91702, 91711, 91722 – 91724, 91731 – 91734, 91740, 91741, 91744 – 91746, 91748, 91750, 91754, 91755, 91765 – 91768, 91770, 91773, 91789 – 91792, 91801, 91803

CCC 50 – Phone (323) 866-6795 / Toll Free (877) 567-9237 / FAX (323) 866-6796

90009, 90051, 90054, 90059, 90061, 90201, 90206, 90220 – 90224, 90231, 90240 – 90242, 90247 – 90250, 90254, 90256, 90260 – 90262, 90266, 90267, 90274, 90275, 90277, 90278, 90280, 90294 – 90296, 90501 – 90510, 90601 – 90606, 90613, 90637 – 90639, 90650, 90651, 90660, 90670, 90701, 90703, 90704, 90706, 90710 – 90717, 90723, 90731 – 90733, 90744 – 90747, 90749, 90801 – 90810, 90813 – 90815, 90822, 90840

5.3 GDSP Contact Information

NT Practitioners Webpage

For general Program information:

Christina Hodgkinson
Program Development and
Evaluation Branch
Genetic Disease Screening Program
Ph: (510) 412 6207
Fax: (510) 412-1560
Christina.Hodgkinson@cdph.ca.gov

To contact the Genetic Disease Screening Program Coordinator:

Siri Stokesberry
Prenatal Screening Program
Genetic Disease Screening Program
Ph: (510) 412-1518
Siri.Stokesberry@cdph.ca.gov

For help logging on to SIS or with user ID or password:

SIS Help Desk: (510) 307-8928
or Christina Hodgkinson (see above)

Appendix A: 1st Trimester Risk Assessment Disclosure & Follow-Up Options

California Department of Public Health - Prenatal Screening Results

Genetic Disease Screening Program
Prenatal Screening Program
850 Marina Bay Parkway, Room F175
Richmond, CA 94804

NT Practitioner Credential #:
NT Practitioner Name:
NT Supervisor Credential #:
NT Site Name:

Clinician ABC
XYZ Facility
1234 Nowry Rd
Richmond, CA 94806
Clinician Phone #: (123) 456-7890
Clinician Fax #: (123) 456-7890

Patient Name : Last, First
Address : 1234 Some Street
Some City, CA 99880-2345
Home Phone : (123) 456-7890
Medical Rec # : 123456
PNS Form # : F000000000A
Accession # : 123-55-000/A -2008-99

Test Results | **Patient Data Used**

Testing laboratory:

MoM = Multiple of Median
PAPP-A MoM: 0.42
based on 735.45 µU/mL
hCG1 MoM: 0.32
based on: 20.65 µU/mL

NT MoM, Fetus 1: 2.0
based on: 3.4 mm
NT MoM, Fetus 2:
based on:

Patient Birth Date: 3/9/1976
Patient Age at Term: 33.00
Ovum Donor? No
Ovum Donor Age:
Patient Weight: 131 lbs
Race/Ethnicity:
HISPANIC/LATINA

Insulin Dependent Diabetic: No
Smokes Cigarettes? Yes

Blood Collection Date:
9/27/2008
Gestational age at blood collection:
12 weeks 2 days
NT Exam Date: 10/5/2008
Gestational age on NT Date: 13
weeks 3 days

Number of Fetuses: 1
Chorionicity:

CRL, Fetus A: 73.4 mm
CRL, Fetus B:

TEST INTERPRETATION FOR 1ST TRIMESTER COMBINED SCREENING

Down Syndrome Risk Assessment: ***SCREEN POSITIVE – INCREASED RISK *** Based on the patient's age and test results, her midtrimester risk is **1 in 49**. This risk is higher than this Program's Down syndrome cut-off which is 1 in 100 at midtrimester.

Trisomy 18 Risk Assessment: ***SCREEN POSITIVE – INCREASED RISK *** Based on the patient's age and test results, her midtrimester risk is **1 in 34.** This risk is higher than this Program's Trisomy 18 cut-off of 1 in 150 at midtrimester. Other reasons for a screen positive result include: very early pregnancy, fetal demise, Trisomy 13, chromosome abnormalities, and pregnancy complications.

ACTION AUTHORIZED BY THE CALIFORNIA PRENATAL SCREENING PROGRAM

Because of the increased risk described above for this first trimester screening, the patient can EITHER accept a referral to a State-approved Prenatal Diagnosis Center for authorized follow-up services, OR draw another blood specimen between 15 weeks 0 days and 20 weeks 0 days gestation to get a Sequential Integrated Prenatal Screening Risk assessment. Contact the Prenatal Screening Coordinator Office listed below to elect either a referral or a second specimen. (There is no additional charge for either option beyond the initial fee for the first specimen.)

Your PNS coordinator's office phone number is (123)456-7890 Issued: 10/05/2008 2:45:41 PM

Genetic Disease Screening Program
Prenatal Screening Program

CLINICIAN LAST, CLINICIAN FIRST
CLINIC NAME
CLINICAN PHONE

Patient Name: LAST, FIRST
Birth Date: MM/DD/YYYY
Accession #: 010-23-104/A -2013-11

FOLLOW-UP OPTIONS AFTER A "SCREEN POSITIVE" RESULT

This information is being provided to you because your ***Screen Positive*** results indicate that your fetus (unborn baby) is at increased risk for a chromosomal abnormality. The risk is based on your Nuchal Translucency ultrasound and the blood test that you had. You have several options for follow-up.

- You may meet with a genetic counselor at a State-Approved Prenatal Diagnosis Center *at no additional charge* to discuss your results and additional testing available to you, which include:
    - Chorionic villus sampling (CVS) between 10 and 14 weeks *at no additional charge*. CVS is a diagnostic test that will tell you whether the fetus you are carrying has an abnormality.
    - Ultrasound and amniocentesis between 15 and 24 weeks *at no additional charge*. Amniocentesis is a diagnostic test that will tell you whether the fetus you are carrying has an abnormality.
    - Non-invasive prenatal testing (NIPT) between 10 and 24 weeks *at no additional charge*. NIPT is a very accurate screening test that will tell you if the fetus you are carrying is at high risk of having certain abnormalities. If you receive a ***Screen Positive*** result for NIPT, you will be offered a CVS or an ultrasound and amniocentesis *at no additional charge* to confirm the results.
    - If you choose one of the three tests described above, you may also choose to have another blood test between 15 and 20 weeks *at no additional charge* to receive a risk assessment for Neural Tube Defects and Smith-Lemli-Opitz syndrome.
- You may have follow-up testing outside of a State-Approved Prenatal Diagnosis Center. You or your insurance company will be billed.
- You may decline a referral to a State-Approved Prenatal Diagnostic Center and choose instead to have another blood test between 15 and 20 weeks *at no additional charge*. This will provide a new risk assessment for Down syndrome and Trisomy 18. Risk assessment for Neural Tube Defects and Smith-Lemli-Opitz syndrome will also be provided. If your result is still ***Screen Positive***, you will be offered ultrasound and amniocentesis or NIPT *at no additional charge*. **Please note that if your 1st Trimester result is *Large NT Screen Positive*, a second blood test will not change this result.**
- You may choose to not have any follow-up at all.

Please contact your clinician regarding your screening result and your decision for follow-up services.

Appendix B: Gestational Age Window for Valid NT Interpretation

The California Prenatal Screening Program

Gestational Age Window for Valid NT Interpretation

NT data will be used for case interpretation when the CRL is between 45–84 mm (gestational age of 11 weeks 2 days through 14 weeks 2 days). CRL measurements will be used for dating purposes when the CRL is between 10–84 mm.

CRL < 9.5 mm	Too early. Have patient reschedule NT appointment.
CRL 9.5–44.5 mm	Have patient reschedule NT appointment and send dating information to referring clinician.
CRL 44.6–84.5 mm	NT data used for case interpretation.
CRL > 84.5 mm	Use BPD to calculate gestational age and send dating information to referring clinician.

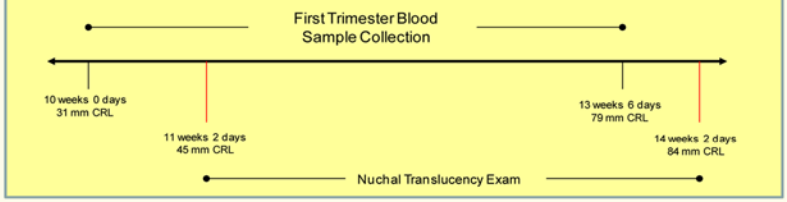
CRL	Gestational Age			CRL	Gestational Age		
(mm)	Decimal	Weeks	Days	(mm)	Decimal	Weeks	Days
31	10.0	10	0	58	12.3	12	2
32	10.1	10	1	59	12.4	12	3
33	10.2	10	1	60	12.5	12	4
34	10.3	10	2	61	12.6	12	4
35	10.4	10	3	62	12.6	12	4
36	10.5	10	4	63	12.7	12	5
37	10.6	10	4	64	12.8	12	6
38	10.7	10	5	65	12.8	12	6
39	10.8	10	6	66	12.9	12	6
40	10.9	10	6	67	13.0	13	0
41	11.0	11	0	68	13.1	13	1
42	11.1	11	1	69	13.1	13	1
43	11.2	11	1	70	13.2	13	1
44	11.2	11	1	71	13.3	13	2
45	11.3	11	2	72	13.4	13	3
46	11.4	11	3	73	13.4	13	3
47	11.5	11	4	74	13.5	13	4
48	11.6	11	4	75	13.6	13	4
49	11.7	11	5	76	13.7	13	5
50	11.7	11	5	77	13.8	13	6
51	11.8	11	6	78	13.8	13	6
52	11.9	11	6	79	13.9	13	6
53	12.0	12	0	80	14.0	14	0
54	12.0	12	0	81	14.1	14	1
55	12.1	12	1	82	14.2	14	1
56	12.2	12	1	83	14.2	14	1
57	12.3	12	2	84	14.3	14	2

30.6 – 44.5 mm
Valid for 1st T blood draw;
too early for NT exam

44.6 – 79.4 mm
Valid for 1st T blood draw
and NT exam

79.5 – 84.5 mm
Valid for NT Exam;
too late for 1st T blood draw.
NT can be used with 2nd T blood

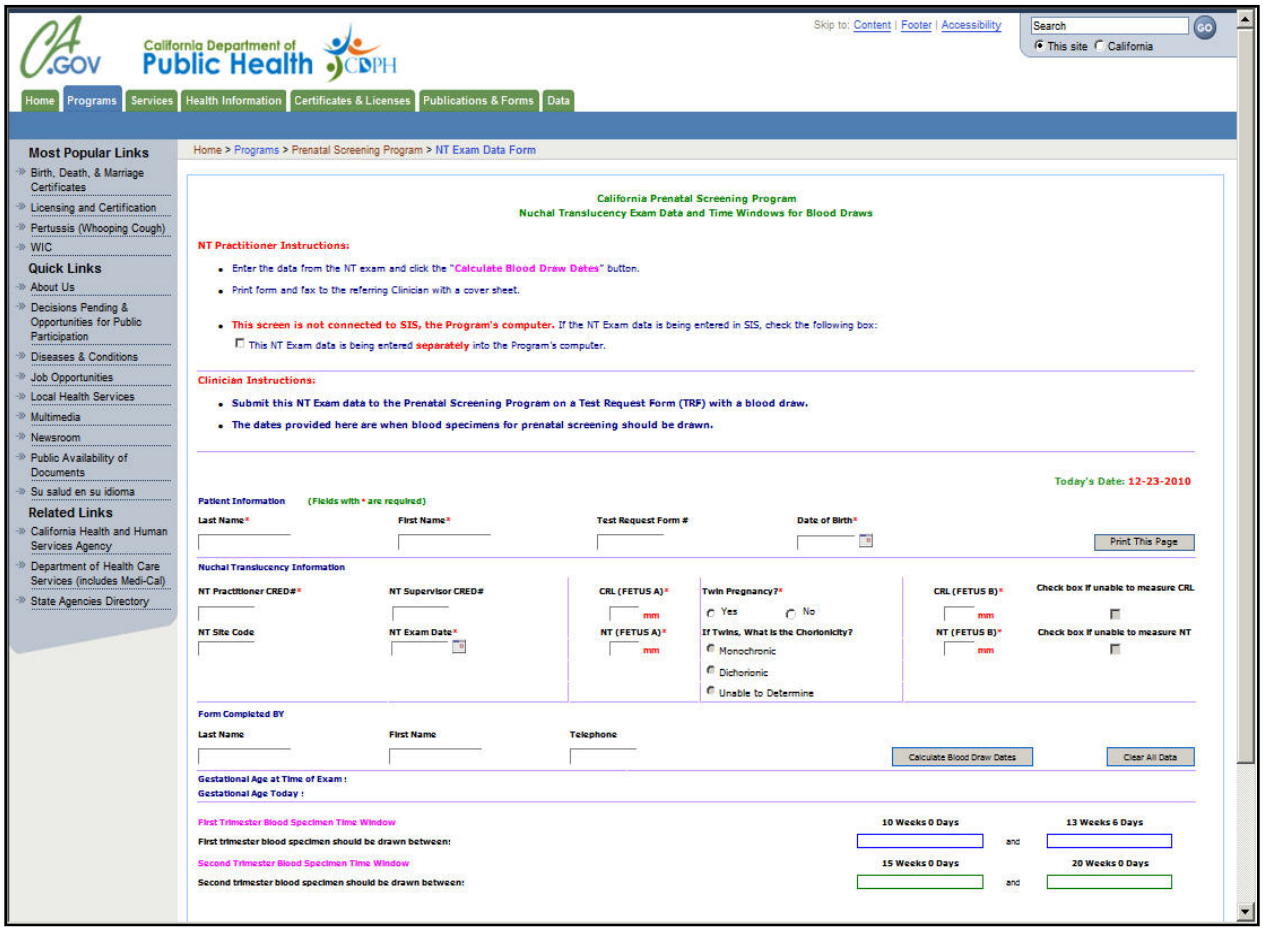
Timeline of 1st Trimester Blood Sample Collection and NT Exam (Gestational Age and CRL)



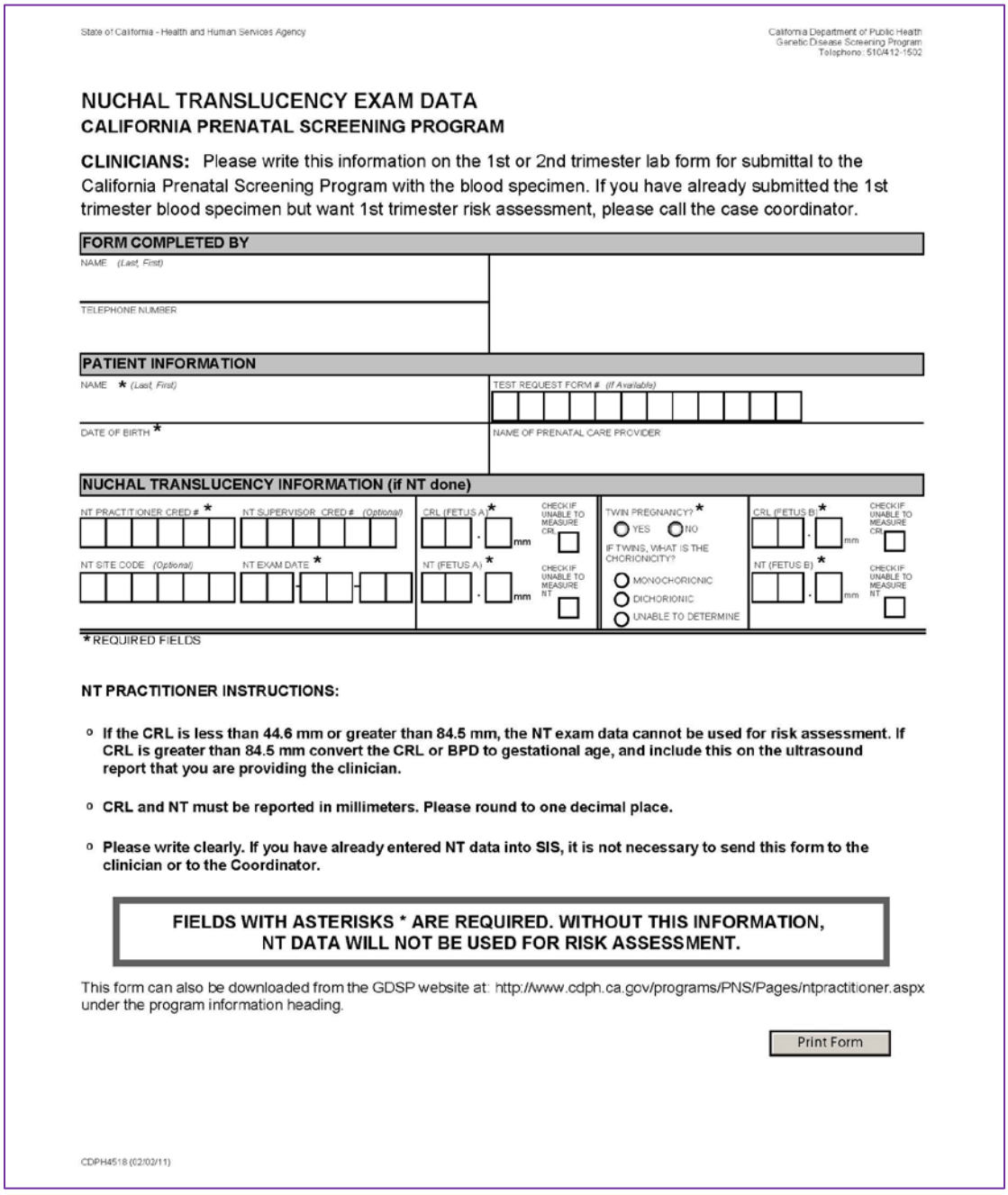
July 2010

Appendix C: NT Exam Data and Time Window for Blood Draws Calculator

(available at: https://cdph.ca.gov/Programs/CFH/DGDS/Pages/ntpractitioners/NT-Calculator.aspx



Appendix D: Form for Submittal of NT Data to Clinician



State of California - Health and Human Services Agency

California Department of Public Health
Genetic Disease Screening Program
Telephone: 510/412-1502

NUCHAL TRANSLUCENCY EXAM DATA
CALIFORNIA PRENATAL SCREENING PROGRAM

CLINICIANS: Please write this information on the 1st or 2nd trimester lab form for submittal to the California Prenatal Screening Program with the blood specimen. If you have already submitted the 1st trimester blood specimen but want 1st trimester risk assessment, please call the case coordinator.

FORM COMPLETED BY

NAME *(Last, First)*

TELEPHONE NUMBER

PATIENT INFORMATION

NAME * *(Last, First)*

TEST REQUEST FORM # *(If Available)*

DATE OF BIRTH *

NAME OF PRENATAL CARE PROVIDER

NUCHAL TRANSLUCENCY INFORMATION (if NT done)

NT PRACTITIONER CRED # *

NT SUPERVISOR CRED # *(Optional)*

NT SITE CODE *(Optional)*

NT EXAM DATE *

CRL (FETUS A) * . mm — CHECK IF UNABLE TO MEASURE CRL

NT (FETUS A) * . mm — CHECK IF UNABLE TO MEASURE NT

TWIN PREGNANCY? * YES NO

IF TWINS, WHAT IS THE CHORIONICITY?

MONOCHORIONIC

DICHORIONIC

UNABLE TO DETERMINE

CRL (FETUS B) * . mm — CHECK IF UNABLE TO MEASURE CRL

NT (FETUS B) * . mm — CHECK IF UNABLE TO MEASURE NT

* REQUIRED FIELDS

NT PRACTITIONER INSTRUCTIONS:

- **If the CRL is less than 44.6 mm or greater than 84.5 mm, the NT exam data cannot be used for risk assessment. If CRL is greater than 84.5 mm convert the CRL or BPD to gestational age, and include this on the ultrasound report that you are providing the clinician.**
- **CRL and NT must be reported in millimeters. Please round to one decimal place.**
- **Please write clearly. If you have already entered NT data into SIS, it is not necessary to send this form to the clinician or to the Coordinator.**

FIELDS WITH ASTERISKS * ARE REQUIRED. WITHOUT THIS INFORMATION, NT DATA WILL NOT BE USED FOR RISK ASSESSMENT.

This form can also be downloaded from the GDSP website at: http://www.cdph.ca.gov/programs/PNS/Pages/ntpractitioner.aspx under the program information heading.

Print Form

CDPH4518 (02/02/11)

Appendix E: Reminders and Suggestions for Efficiently Providing NT Data

The most important suggestion is to establish a system with your referring prenatal care providers/clinicians. The following suggestions are systems that are currently successfully working for many NT practitioners and their referring clinicians. Please communicate with your referring clinician base to determine which system works best for your patients.

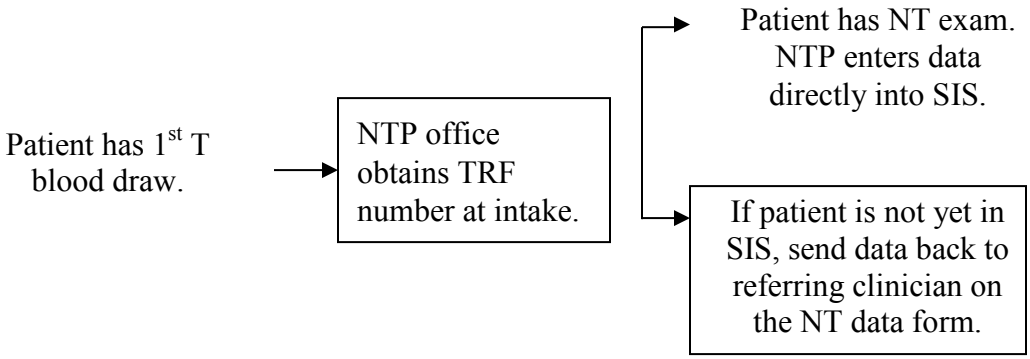
A. For patients who have their NT ultrasound <u>after</u> their blood is drawn

- Encourage the prenatal care provider to **draw the blood specimen at least one week ahead of time**, so the test results can be immediately combined with the NT results.

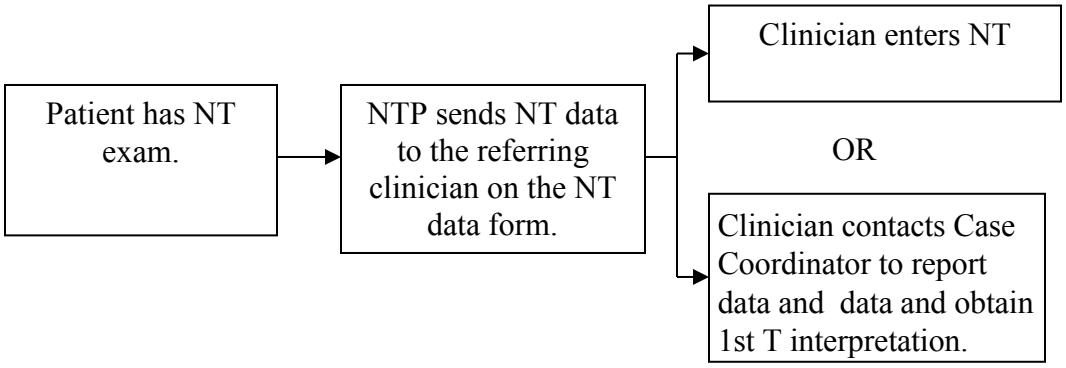
- **TRF #:** Have your **appointment intake form and referral form include a line for the form number** of the Prenatal Screening Test Request Form (TRF #). If the patient does not bring in her TRF#, please call her referring clinician (not the Coordinator) to obtain the TRF # and remind them to put it on the referral form.

- **Please inform your referring clinicians if you are NOT going to exercise the option to enter NT data directly into SIS.** Fill out the *Nuchal Translucency Exam Data Form* (NT form) and return it (fax it) to the referring clinician. (Do **NOT** just send the original record from the ultrasound machine – clinician staff does not always read this correctly.) Please make sure to obtain and include the TRF # on the NT form.

- **If you are a SIS user**, please follow the protocol to enter the NT information. If the patient's pregnancy is not yet in SIS, please fill out the NT data form and return it to the clinician.



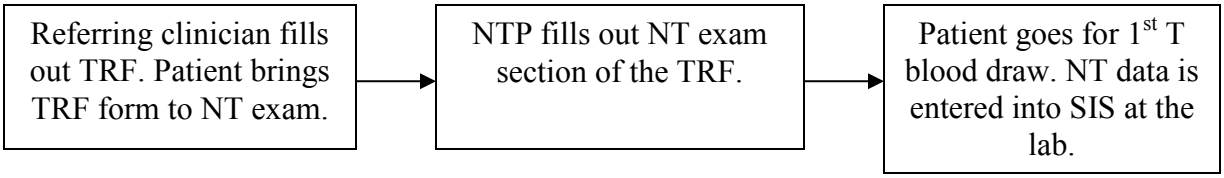
- If you are not a SIS user, or if you do not have the TRF number, please fill out the NT data form and return it to the clinician.



- The Prenatal Screening Coordinator can assist with occasional problematic cases, but **it is not the role of the Coordinator to routinely enter NT data for NT Practitioners or to track cases not yet in SIS.**

B. For patients who have their NT ultrasound <u>before</u> their blood is drawn

- **Ask the referring clinician to completely fill out a Test Request Form** (except for NT data and Blood Collection Date) **and give it to the patient to bring to her NT appointment.** You should add the NT data to the TRF and send the patient for the blood draw. The clinician will get a screening result, including NT, about one week after the blood is drawn.



- **For the patient who does not bring a TRF to her NT exam:**
  Fill out the *Nuchal Translucency Exam Data Form* (NT form) and fax it to the referring clinician (not the Coordinator). The clinician will put the NT data on the patient's 1st Trimester TRF and send her for blood draw.