California Department of Public Health

Genetic Disease Screening Program

Prenatal Screening Program

Quick Reference Manual for Nuchal Translucency (NT) Practitioners

This manual was produced by:

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

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Purpose of this Manual

This manual is provided by the California Prenatal Screening Program (the Program) as a reference for Nuchal Translucency Practitioners participating in the Program. This abbreviated version is a summary of the information presented in the *Comprehensive Manual for NT Practitioners.* The detailed manual can be found at the NT Practitioner Web-page. Additional tools for formatting and validating NT Exam data submitted to the Prenatal Screening Program are also located on this web-page.

For further information concerning NT Exams in the Prenatal Screening Program, a list of contacts and telephone numbers is on page 9 of this manual.

This manual includes policies on and directions for:

- 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

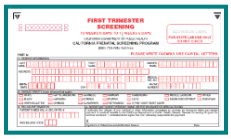
Submitting Data to the Program

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

NT Practitioners can submit NT data in three ways:

Logon to SIS and enter data directly into SIS for immediate interpretation of results.

Send data to clinicians via fax or email. Clinicians then incorporate data into patient files and submit it to SIS on Test Request Forms (TRFs).



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 designated Prenatal Screening Coordinator listed in Chapter 5 of the Comprehensive Manual.

In order for NT data to be used in risk assessment, you must include:

- The patient's name and date of birth, and TRF Number
- NT Practitioner Credential ID
- NT Exam Date
- Crown-Rump-Length (CRL) in mm
- NT in mm
- 'Is This a Twin Pregnancy?' (Yes/No)
- If this is a twin pregnancy, chorionicity must be provided. (See Page 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.

SIS Error and Status Messages

SIS Message or Status	Reason/Action
SIS search screen displays “Case not found. Send information to referring clinician.”	Patient information has not yet been entered into SIS. Send NT data to the referring clinician. **NOTE: 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.**
SIS search screen displays “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 displays 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 displays “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 displays "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 screen displays “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.

SIS Error and Status Messages

SIS Message or Status	Reason/Action
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.
When you try to save a CRL measurement that is 9.5 mm – 44.5 mm, the SIS screen displays "Patient gestational age is out of range for use of NT in risk assessment."	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.**

Twin Pregnancies and Other Findings in NT Exams

Twins
If you identify a twin pregnancy, you must also indicate if the twins are monochorionic or dichorionic or if the chorionicity cannot be determined. You must enter numeric values for both the CRL and NT for at least one twin, Fetus A or Fetus B. For the other fetus you may enter "Unable to Measure" for the CRL or the NT or both.

When both fetuses have measurable CRLs, the larger one is always used for gestational age dating for the purposes of screening.

Fetal demise may affect the interpretation of blood analyte results. If there is evidence of fetal demise refer to the following table for appropriate procedures.

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 2ndTrimester screenings are available for this pregnancy (if patient's blood was drawn during the appropriate time-frame) 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.	1stTrimester 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 surviving 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.

Scheduling NT Exams & Blood Draws to Facilitate SIS Data Entry

In order to enter NT exam data directly into SIS, a record for this pregnancy must already be in the system, and you must have the patient's TRF number or accession number. The record is created by the lab when it processes the First Trimester blood specimen. So the blood draw should be done several days before the NT exam. You may need to work with your referring clinicians to arrange patient flow accordingly.

Preferred schedule for blood draws and NT exam

- Patient's First Trimester blood draw should be during gestational week 10 or 11 (CRL from 30.6 mm to 52.5 mm)
- Clinician's office includes patient's TRF number when scheduling the NT exam
- Patient's NT exam performed at least 7 days after her blood draw (CRL from 44.6 mm to 84.5 mm)
- Patient's First Trimester Preliminary Risk Assessment is usually available immediately on the SIS screen
- Patient's Second Trimester blood draw should be scheduled during gestational weeks 15 through 20, based on the NT-CRL

When the patient has not had her blood drawn before the NT exam

- If the patient has her TRF
  - Write the NT exam data on the TRF
  - Give the TRF to the patient to take to the lab where her blood specimen will be drawn
- If the patient does NOT have her TRF
  - Enter the NT exam data on one of the NT Exam data recording tools from the NTP Web-page
  - Fax or email the form to the referring clinician
  - Referring clinician will give the data to the program

SIS Messages that may occur due to patient flow issues

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 the patient regarding her 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.*

*When the NT measurement is ≥ 3.0 mm, the case will be ***Large NT Screen Positive***, regardless of the blood specimen results. If you encounter this situation, please call the Case Coordinator.

Viewing and Communicating Your Patient's Prenatal Screening

After you have saved the NT Exam data for a patient, you have the option of viewing her result interpretation and risk assessment. If you choose not to view the result interpretation, the Case Coordinator will follow-up with the referring clinician. Your patient will obtain her screening result from her referring clinician.

Screen Negative results are available immediately. If there is incomplete information in your patient's record, SIS will direct you to contact the Case Coordinator in order to provide the missing information and obtain a result.

Pregnancies with a risk greater than 1 in 100 for Down syndrome or a risk greater than 1 in 150 for Trisomy 18 are ***Screen Positive.*** When the NT measurement is large (≥ 3.0 mm) the pregnancy has a risk greater than 1 in 5 for chromosomal abnormalities or cardiac defects and is ***Large NT: Screen Positive***. In order for you to view a ***Screen Positive*** result, you must contact the Case Coordinator to confirm the screening information.

When you call the Case Coordinator and confirm a ***Screen Positive*** result, you are responsible for informing the patient of her ***Screen Positive*** result and the available follow-up options. A page detailing the patient's options for follow-up will print with the Screening Information System (SIS) results. Examples of both pages are available in the *Comprehensive Manual for NT Practitioners*. You must review the options with the patient and provide a copy of both pages to her.

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

Gestational Age Dating based on the NT Exam Data

The Prenatal Screening Program has a clearly defined timeframe for the gestational age windows of the First Trimester blood draw, NT exam and Second Trimester blood draw. The Program uses the Hadlock 1992 conversion table as the only method to convert CRL into GA. **A GA that is a single day different than the one obtained using the Hadlock conversion could result in a blood specimen being outside the time window for prenatal screening.**

The Prenatal Screening Program always bases gestational dating on the NT CRL if it is available. Once the NT exam data is entered into our system, the pregnancy is dated according to the Hadlock conversion of the NT CRL for the entire screening process. It is important that NT data be submitted to the Program as soon as possible so that blood draws can be scheduled accordingly.

When the results of an NT exam are faxed to the referring clinician, please include the gestational dating based on the NT-CRL, converted to gestational age using the Hadlock 1992 algorithm. To assure that the patient and the referring clinician are aware of the correct time window, use one of the following tools provided on the program's NT Practitioner Web-page:

- **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 the patients' blood draw time windows. The dates can be printed out for both patients and referring clinicians.
- **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.

Contacting the Prenatal Screening Program

Questions about NT Practitioner credential status

Contact your credentialing agency:

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

Questions about a patient's record or screening data

Contact the Case Coordinator listed on the SIS screen or screening information printout. Coordinators are assigned to cases by the ZIP Code of the referring clinician. Tables 5.1 and 5.2 in the *Comprehensive Manual for NT Practitioners* list the Coordinator assignments and phone numbers.

Questions about Prenatal Screening in California (Genetic Disease Screening Program)

For Program information or information on how to enroll as a SIS User:

Toki Fillman
Program Evaluation and Development
Ph: (510) 620-6228
Fax: (510) 412-1560
Toki.Fillman@cdph.ca.gov

To contact the Genetic Disease Screening Program Coordinator:

Monica Flessel, Chief
Prenatal Screening Program
Ph: (510) 412-1456
Monica.Flessel@cdph.ca.gov

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

SIS Help Desk: (510) 307-8928