

# Protocol for Expedited Phenylalanine (Phe) Monitoring

## POLICY:

1. The Genetic Disease Laboratory Branch (GDLB) will expedite the reporting of Phe Monitoring results when requested by CCS-approved Metabolic Centers. The Metabolic Center shall make an request to expedite by attaching an URGENT label to the TRF.
2. It is recognized that some testing requires expedited reporting of results. These include the first two specimens at the initiation of Kuvan treatment, the weekly specimens collected from pregnant patients with PKU and specimen from newly diagnosed newborns.
3. All specimens shall be collected and sent to GDLB according to this protocol. **Testing at GDLB is done on non-holiday weekdays only; no testing is done on weekends or holidays.**
4. In order to maximize the benefits of expediting the result reporting, specimens should be collected and shipped Monday – Thursday. Specimens should be sent to GDLB using the prepaid GSO overnight labels to minimize transit time.
5. All specimens received by GDLB will be accessioned and entered into SIS the same day they are received. They will appear on the case summary page in the “Additional Results” grid. Test result will be reviewed and reported to the metabolic center the same day. So a specimen received on Tuesday before noon, will be reported via phone late Tuesday afternoon.
6. Test results will post to SIS on the regular schedule and appear the second day after accession (ex. A specimen received on Tuesday before noon is accessed and the TRF information is entered into SIS on Tuesday. Specimen is run on Tuesday, and reviewed, and verbally reported to the metabolic center by phone on Tuesday. The file is passed to SIS on Wednesday. Results will be available for viewing in SIS on Thursday morning).
7. A Result Mailer will be sent to the specimen collection facility indicated on the form.

## PROTOCOL:

Resp. Person	Action
GDSP Warehouse Staff	<ul style="list-style-type: none"> <li>• Distributes <i>Test Request Form For Phe Monitoring Test</i> and pre-paid, pre-addressed mailing envelopes to Metabolic Centers upon request.</li> </ul>
GDSP Program staff	<ul style="list-style-type: none"> <li>• Arranges for the delivery of prepaid GSO Overnight Delivery labels addressed to GDLB to the metabolic Center.</li> <li>• Distributes red URGENT labels to Metabolic Center</li> </ul>
Metabolic Center Staff	<ul style="list-style-type: none"> <li>• Distributes GSO Overnight Delivery labels &amp; URGENT labels to patients who will require expedited reporting of results.</li> </ul>
Person collecting specimen	<ul style="list-style-type: none"> <li>• Completes all demographic fields on the <i>Test Request Form for Phe Monitoring Test</i>, following instructions on the front of the form.</li> <li>• Applies URGENT label to front side of TRF</li> <li>• Collects the blood specimen on Monday – Thursday.</li> <li>• Collects blood specimen on the <i>California Newborn Screening Specimen Collection Card</i>, following instructions on the back of the card.</li> <li>• Spots the first three circles with blood.</li> </ul>

	<ul style="list-style-type: none"> <li>• Dries specimen completely.</li> <li>• Sends original white sheet of TRF along with the specimen to Genetic Disease Laboratory (GDL) using GSO courier label on a Monday – Thursday.</li> <li>• Can use another overnight courier at the patient own expense. Sends package to: Genetic Disease Laboratory 850 Marina Bay Parkway, C227 Richmond, CA 94804</li> </ul>
GDLB Accessioning Staff	<ul style="list-style-type: none"> <li>• Identifies specimen as needing expedited result reporting based on URGENT label on TRF.</li> <li>• Accessions specimens and applies URGENT label to specimen card/cassette.</li> <li>• Advises GDLB analyst that PHE a PHE monitoring specimen in the day's group has an URGENT label and needs expedited results reporting.</li> </ul>
GDLB analyst and supervisor	<ul style="list-style-type: none"> <li>▪ Runs analysis and reviews run</li> <li>▪ Once run is approved calls metabolic center assigned to specimen marked URGENT.</li> <li>▪ Reports PHE Monitoring results</li> </ul>
Metabolic Center ordering Phe Monitoring	<ul style="list-style-type: none"> <li>▪ Receives verbal results by phone from GDLB analyst.</li> <li>▪ Reviews results in SIS.</li> <li>▪ Files Result Mailer in medical record, when received.</li> </ul>