

Appendix F  
Newborn Screening Matrix  
RFP # 5710 Z1

RFP Section Number	Requirement	Accept (Initial)	Reject (Initial)	Reject & Provide Alternative within RFP Response (Initial)	Notes/Comments:
V.C.33	<p>For each condition screened, the instrumentation, method, screening algorithm or cut-offs must be clearly described. Flow-chart/algorithms to illustrate the test result reporting criteria are encouraged, but should not be considered an adequate replacement for a narrative, detailed description. The methods used must follow presently accepted good laboratory practice and be compliant with FDA, and CLIA regulations, and if available FDA approved products should be used. FDA cleared products are acceptable. Methods should have been routinely used by newborn screening programs for at least one (1) year and their performance documentation exists in Quality Control reports from CDC. For proprietary information, the proposal must provide a general overview, and assurance that written protocols, interpretation criteria and screening algorithms will be provided in writing to the NNSP within 30 days following contract award date. Bidders must complete Appendix B.</p>	<p>Complete <b>attached table below</b> for response to this requirement. **</p>			

Appendix F  
Newborn Screening Matrix  
RFP # 5710 Z1

V.C.34	For which disorders within these classifications, beyond those listed in Section V.C.1 - 30, their laboratory can reliably detect via tandem mass spectrometry or other multiplex testing and describe the informative markers evaluated and cut-offs or screening algorithms used to determine the need for additional follow up. The table in Appendix B must be completed identifying for each condition or analyte screened the number of specimens screened, number of abnormal screens reported out, and the number of confirmed conditions associated with that screen during the prior 2 year period. If the current method/algorithm has been used for less than 2 years, the available data described above, since using that method/algorithm.	Complete <b>Appendix B</b> for response to this requirement			
V.C.35	If any of this required information is proprietary, the following applies: By virtue of submitting a proposal the bidder agrees that if awarded the contract, the proprietary information will be provided to the NNSP within 30 days following contract award date.				
V.C.36	Data for the laboratory regarding the false positive rate per year for each of the tests performed, (see tables in Appendix B), the percent of filter paper blood specimens identified as unsatisfactory and the reasons for rejection, the turn-around time from specimen receipt to reporting of results. Data for the laboratory regarding the false negative rate, explanations for errors and remedial actions. (Complete tables in Appendix B) and return with bidder's proposal response.	Complete <b>Appendix B</b> for response to this requirement			

Appendix F  
Newborn Screening Matrix  
RFP # 5710 Z1

V.C.37	For each analytical methodology and instrument used, available methods for backup/confirmation. (e.g. Beuter and Baluda back-up for Biotinidase testing if primary testing instrument were to be unavailable).	<b>Complete attached table below for response to this requirement. **</b>			
V.C.38	If not already described in Section V.C.1-30, specify any 2nd tier or reflex testing (E.g. a different test with a new punch from the same sample) proposed as part of the screen. If DNA is used as a 2nd tier or reflex test, specify which mutations or polymorphisms are tested for or if sequencing is proposed. The Department of Health and Human Services reserves the right to determine if sequencing will be allowed as part of the screening algorithm for any condition screened. (Include in response to B).				
V.C.39	For which type of results (e.g. unsatisfactory specimens, inconclusive or preliminary positive test results for “x” condition) a repeat dried blood spot filter paper specimen would be requested (vs. confirmatory serum, plasma or other test). Requested repeats for specimens collected at less than 24 hours, that are unsatisfactory, collected post transfusion, required due to infant’s birthweights being less than 2000 grams, are indeterminate because of multiple elevations of amino acids indicating hyperalimentation, or requested because of inconclusive findings shall not be charged for separately.				

Appendix F  
Newborn Screening Matrix  
RFP # 5710 Z1

V.C.40	Describe any other newborn screening and confirmatory tests not described in Section V.C .1-30, available in bidder's laboratory; including for screening tests, the estimated incidence of the disorder and the observed incidence in bidder's laboratory. Include the false positive and false negative rate per year for each of these additional screening tests. Provide a separate schedule of costs for the addition of these tests. The schedule should list the additional cost for each individual test, and if available, the cost for groups of tests (e.g. multiplex format) for similar disorders.				
V.C.41	Available, state of the art methodologies that may be currently used under research protocols or as a pilot. If it is the bidders intent to make this available to the NNSP, the test(s) should be detailed in regard to instrumentation, analytical staff, oversight, experience, backup, and ability to provide clinical consultation regarding the interpretation of new testing data.				
V.C.42	Individually, list all analytical instruments available for this project, specifying if leased or owned, their age and support agreements (including repair histories, and average time for repair), current workload with these instruments, back up capabilities (such as duplicate instruments) and the laboratory's capacity to add the workload from the Nebraska newborns to be screened. Instrument replacement plans for aging equipment should also be described.				
V.C.43	Other conditions may be detected by the acylcarnitine and amino acid profiles of tandem mass spectrometry beyond those included in the list from Section V.C.1-30. The bidder shall list other conditions that may be able to be detected by the proposed screening protocol.				

Appendix F  
Newborn Screening Matrix  
RFP # 5710 Z1

**\*\*Complete this table for response to V.C.33 and V.C.37.**

Condition Screened	Instrumentation V.C.33	Method V.C.33	Screening algorithm V.C.33	Cutoffs V.C.33	Flow Chart attached? V.C.33	Narrative description of algorithm V.C.33	Back up Methodology and instrument used in the event of equipment failure by the primary method. V.C.37
Arginininosuccinic acidemia (ASA)							
BIO							
CAH (17-OHP)							
CF (IRT/DNA)							
CIT (Cit)							
CPH (T4/TSH)							
CUD(low C0)							
GA-I (C5DC or C10-OH, or C8 + C10)							
GAL (Gal/GALT)							
HCY (Met & Homocy)							
Hgb's S, SC, Thal's							
HMG (C5:OH, C6:DC w/ C5:OH)							
IVA (C5, C6-DC, w/ C5-OH)							
LCHAD (C16-OH, or C18:10OH with others)							
MSUD (Val, Leu, and/or Isoleucine)							
MCAD (C8, or C8 with others)							
MMA (C3, C3:C2, C3:C16)							

Appendix F  
Newborn Screening Matrix  
RFP # 5710 Z1

MMA cbl A, B (C3, C3:C3OH, C4DC, Met)							
MPS-I (IDUA)							
MCD (C3 or C5OH)							
PKU (Phe, Phe/Tyr)							
PD (GAA)							
PA (C3,C3:C2, C3:C16)							
SCID (TRECS)							
Tyr (Tyr)							
TFP C16-OH, C18:1-OH with C16-OH)							
VLCAD (C14, C14:1, C14:2, & C14:1/C12:1)							
X-ALD (C26.OLC)							
3-MCC (C5:OH or C5:1 w/ C5:OH)							
Other MS/MS findings							