

Scope of Work:

The Alabama Bureau of Laboratories screens newborns for a number of congenital disorders and wants a single vendor to supply instruments, reagents, instrument service, and software to test newborn dried blood spots for the following congenital disorders:

- Congenital Hypothyroidism (CH) measuring TSH and T4),
- Congenital Adrenal Hyperplasia (CAH) measuring 17 α OH Progesterone (17OHP),
- Cystic Fibrosis (CF) measuring Immuno-reactive Trypsin (IRT)
- Galactosemia measuring galactose-1-phosphate urydl transferase (GALT) activity and Total Galactose (TGAL) as optional confirmation or dual initial screen
- Biotinidase Deficiency (BIO) measuring Biotinidase as an option.

This will be an all or nothing award.

Pricing shall be: one of the options below

1. Included in the price of the reagents kits shall be:
 - Instruments and accessory equipment with service contracts
 - DBS punching equipment with include service contracts,
 - Process Management and Data Analysis Software including licenses, configuration, training and maintenance. Hardware will be provided by the laboratory.
 - Consumables
2. Monthly Fee for instruments, reagents, software and service for TSH, T4, CAH, IRT, and GALT. BIO and TGAL to be purchased as individual kits with any additional instrumentation, instrument service or software configuration included in price of the kit.

The laboratory tests 128,000 specimens per year.

Specifications:

A: Reagent kits: as listed below or equivalent

TSH: AutoDELFI Neo TSH: PerkinElmer #B032-312 (1152 tests) or GSP NeoTSH PerkinElmer #3301-001U

T4: AutoDELFI Neo T4: PerkinElmer # B065-112 (1152 tests) or GSP Neo T4 PerkinElmer #3302-001U

CAH: AutoDELFI Neo 17 α OH Progesterone: PerkinElmer # B024-112 (1152 tests) or GSP Neo T4 #3305-001U

IRT: AutoDELFI Neo IRT : PerkinElmer # B005-112 (1152 tests) or GSP Neo IRT, PerkinElmer #3306-001U

GALT: NCS GALT (Victor), PerkinElmer part # NG4100 (4800 tests) or GSP Neo GALT, PerkinElmer # 3303-001U

GAO: NCS Total Galactose (Victor), PerkinElmer part#3029-0010 (960 tests) or #3029-001B (4800 tests)

BIO: NCS BIO (Victor), PerkinElmer #3018—001B (4800 tests) or GSP BIO, PerkinElmer #3307-001B

Requirements:

- ◆ TSH, T4, 17 OHP, IRT and GALT kits must be FDA approved for use on instruments specified in product insert.
- ◆ TR-FIA or Fluorescent methods (not RIA or ELISA methods)
- ◆ Each assay kit includes DBS 6 standards or calibrators and a minimum of 2 controls, high and low values, on Whatman 903 paper or equivalent.
- ◆ Microtiter plate based with plate barcodes for assay identification
- ◆ 1/8 inch dried blood spot per well
- ◆ All reagents and plates included in kit or shipped separately
- ◆ Same day analysis time – incubations of < 5 hrs (1 plate runs)

- ◆ Vendor is the manufacturer of the reagent kits.
- ◆ AutoDELFIA, Victor or GSP versions of TSH, T4, 17 OHP, IRT, and GALT, kits have been In use for initial Newborn Screening by more than 5 state DOH Newborn Screening testing laboratories with birth rates of >50,000 for more than 3 years.
- ◆ AutoDELFIA, Victor or GSP versions of TSH, T4, 17 OHP, IRT and GALT kits have demonstrated at least 3 years of satisfactory performance on CLIA approved proficiency testing (PT) e.g. CDC QA/QC newborn screening program.

B: Instrument Systems:

Field service performed by direct employees of the vendor to include but not limited to Preventive Maintenance as recommended by vendor.

Response times:

- response to phone to report problem: 3 hours
- service engineer on site within 2 business days.

1. 4 AutoDELFIA PlateProcessor Automated Systems: PerkinElmer # 1235-501 or or equivalent. *For T4, 17OHP , TSH, IRT assays*

Requirements:

- ◆ Total walk-away automation
- ◆ Runs unattended (completes assays after working day has ended)
- ◆ 12 microtiter plate capacity up to 1152 test results
- ◆ Assay microplates can be mix of 4 assays to include T4, TSH and 17OHP without intervention by operator
- ◆ Reads plate barcodes
- ◆ Makes reagent dilutions
- ◆ Onboard instrument diagnostics
- ◆ History file of all system operation
- ◆ Capable of bi-directional interface to Process Management software
- ◆ Windows environment
- ◆ Data Analysis software with the following capability:
 - Track up to 6 levels of controls per assay, generate Levy-Jennings plots and histograms, track and plot standards.
 - Accept laboratory cutoff and generate warning flags.
 - Sort and generate repeat list based on cutoff values.
- ◆ Remote support for service and software
- ◆ Pumps waste to drain
- ◆ Uninterrupted Power Supply for protection from brief power failures and brown-outs.
- ◆ All reagents and wash buffers used with assay included in price of kit.
- ◆ Laser printer for each instrument.
- ◆ Listed as specified instrument in assay product inserts.
- ◆ System has been In use for initial Newborn Screening by more than 5 state DOH Newborn Screening testing laboratories with birth rates of >50,000 for more than 3 years.
- ◆ Vendor is the manufacturer
- ◆ Field service performed by direct employees of the vendor to include Preventive Maintenance as recommended by vendor.

2. Victor D with Stackers: PerkinElmer LAS part # 1420-021 or equivalent *For GALT, TGAL and BIO assays*

Requirements:

- ◆ Has capability of reading TR-FIA and FIA methodologies.
 - ◆ Holds up to 12 microtiter plates for unattended reading, not a flow through technology.
 - ◆ Reads plate barcodes
 - ◆ Has remote support capability.
 - ◆ Manufactured by vendor
 - ◆ Capable of bidirectional interface to Process Management software
 - ◆ Includes: data analysis software, computer, monitor, laserjet Printer.
 - Data Analysis software with the following capability:
 - Track up to 6 levels of controls per assay, generate Levy-Jennings plots and histograms, track and plot standards.
 - Accept laboratory cutoff and generate warning flags.
 - Sort and generate repeat list based on cutoff values.
 - Reevaluation of stored data
 - ◆ System has been in use for initial Newborn Screening by more than 5 state DOH Newborn Screening testing laboratories with birth rates of >50,000 for more than 3years.
3. Optional to Systems listed above:
- 3 GSP Instrument Systems: PerkinElmer #2021-0010 or equivalent.
- Instrument system must be FDA cleared and specified in reagent kit package insert.
 - There may be a mix of instrument systems listed in 1, 2 and 3 during the term of the contract as assays are FDA cleared on the upgraded instrument system. Vendor to outline an implementation plan.

C: Accessory Instruments/Equipment

Field service performed by direct employees of the vendor to include: Preventive Maintenance as recommended by vendor.

1. For use with the NCS GALT, BIO and TGAL on the Victor System or equivalent.
 - a. Incubator Shakers to process 9 plates of each assay at the temperature and shaking speed specified in the package insert.
 - b. 1 Apricot Personal Pipettor, Perkinelmer or equivalent

Requirements:

 - ◆ capable of pipetting 96 wells simultaneously
 - ◆ Minimum of 4 stations,
 - ◆ Performs transfer pipetting
 - ◆ Includes software, computer and monitor if required
 - ◆ Pipette tip packs purchased separately as part of contract.
 - ◆ Reagent Boats purchased separately as part of contract.
2. 1 PerkinElmer MultiPuncher part # 1296-081 or equivalent

Requirements:

 - ◆ The instrument must have a minimum capacity of six-plates.
 - ◆ Must have the ability to punch 3.2 mm filter paper spots
 - ◆ Must allow operator to punch specimens in singlicate or duplicate format.
 - ◆ Instrument must be connected to a computer via an RS-232 port.
 - ◆ Software must be a 32 bit application running in a minimum of Windows XP

- ◆ Must have positive sample and plate identification provided by a barcode reader that is connected to a computer.
 - ◆ Capable of bi-directional interface to Specimen Gate™ Process Management software.
 - ◆ Computer provided by vendor
 - ◆ Must be able to support standard 96-well microtitration plates.
 - ◆ Must have a disk detector system that ensures that a spot falls into the well.
 - ◆ Must blow down air through the punchhead to facilitate punching of spot into the well.
3. 2 PerkinElmer DBS Puncher part # 1296-071 or equivalent
- Requirements:
- ◆ Capable of multiple sized punch heads to include 1.5mm, 3.2mm, 4.7mm and 6.0mm spots. These heads must be easily removed by the operator in less than 30 seconds.
 - ◆ Operates in a stand alone mode and computer controlled.
 - ◆ Programmed by either a PC or by a touch pad built into the instrument.
 - ◆ Positive ID function through barcode reading of plate and specimen during punching.
 - ◆ Capable of bi-directional interface to Specimen Gate™ Process Management software
 - ◆ Alerts the operator to a possible missed spot, and allow the operator to take corrective action.
 - ◆ Holds 2 microtiter plates, standard or deep well.

D: Process Management Software

Specimen Gate™ Laboratory or equivalent. If equivalent, the vendor must supply a detailed description of the system. A demonstration may be requested.

1. The software must interface to all instrument systems and punchers listed in these specifications as well as the Waters/PerkinElmer Quattro Micro MSMS system.
2. Deployment and Training: If an equivalent system,
 - A Project Plan including timeline and training must be included with the
 - User Manuals to be provided
3. Maintenance
The vendor must provide maintenance and on-going training as requested with direct report engineers.

Exception to this will be tips and reservoirs for automated pipettor and required microtiter plates for reagent transfer step. These will be purchased as separate line item.

Pricing Option 1:

	Unit Price	Quantity/yr	Total/year
1. Neonatal TSH: 161,280 tests/yr:	_____	_____	_____
2. Neonatal T4: 161,280 tests/yr:	_____	_____	_____
3. Neonatal 17 OHP: 161,280 tests/yr:	_____	_____	_____
4. Neonatal IRT: 161,280 tests/yr:	_____	_____	_____
5. Neonatal GALT: 140,000 tests/yr:	_____	_____	_____
6. Neonatal Total Galactos:e as needed:	_____		_____
7. Neonatal Biotinidase: as needed:	_____		_____

Consumables:

8. Autopipette tips: PerkinElmer part# 1295-4010

Estimated number of packs/yr: _____ price/pack _____

9. Autopipette Reservoirs: PerkinElmer part# 1064-05-08

Estimated number of packs/yr: _____ price/pack _____

Pricing Option 2:

Please submit plan separately to include:

- Monthly fee, number of tests/kits and consumables included annually for T4, TSH, CAH, IRT and GALT
- Price of kits if additional kits of T4, TSH, CAH, IRT and GALT are to be purchased within the year.
- Price of BIO and TGAL kits (not included in monthly fee).