TEXAS Department of State Health Services

Biochemistry and Genetics Branch Update

Rachel Lee

November 12, 2012

Fall Conference of Public Health Laboratory Directors of Texas

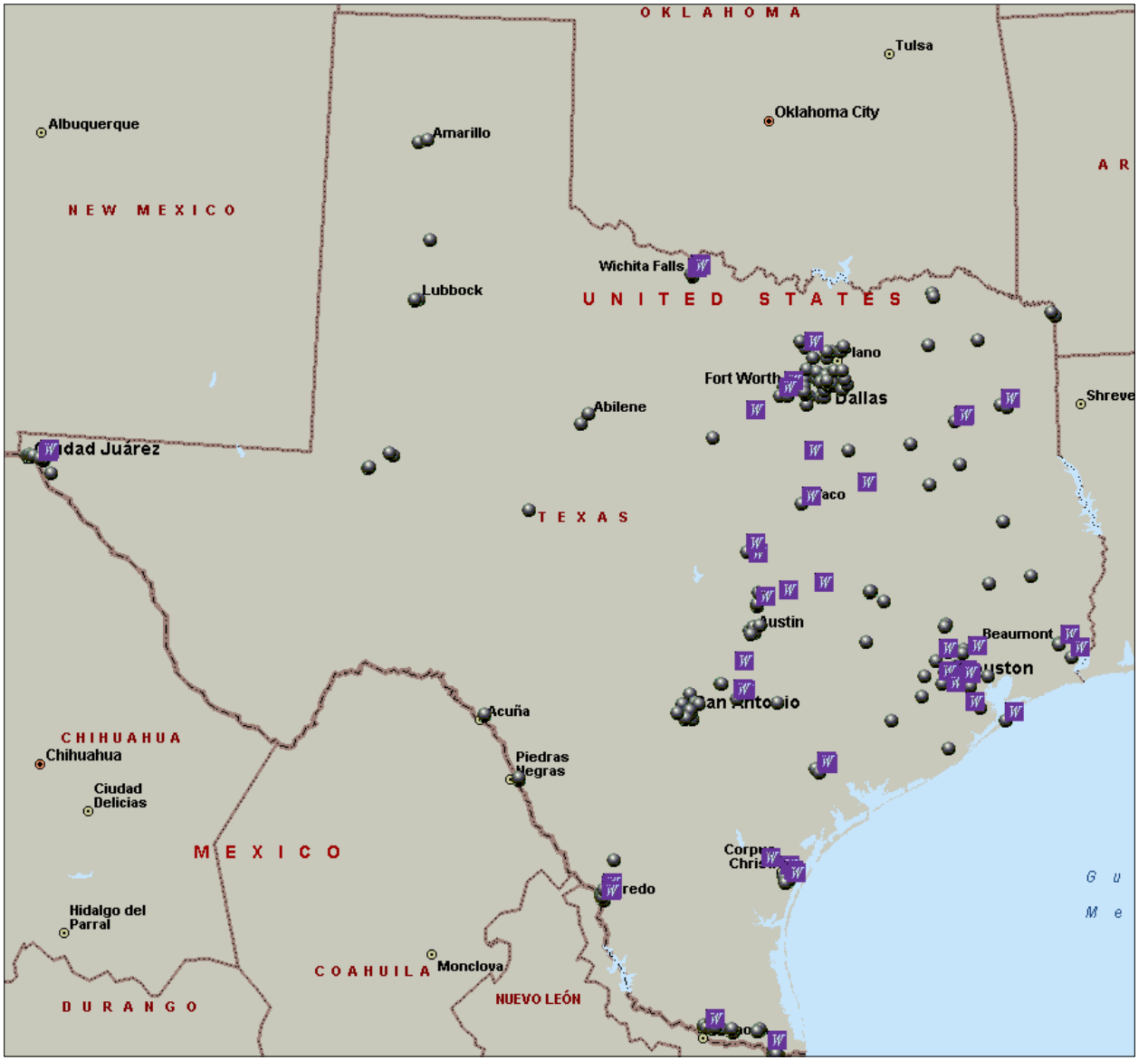
Overview

- Laboratory Courier
- Clinical Chemistry
- Newborn Screening

Courier Pilot Project

- Full-service courier
  - Routes include Dallas, Fort Worth, Houston, Beaumont, Tyler, Texarkana, Wichita Falls, Brenham, San Antonio, Brownsville, McAllen, Laredo, Del Rio, Corpus Christi, Austin, Temple, Waco, San Angelo, Midland, Odessa, El Paso, Lubbock, Amarillo
- Total Sites As of 11/12/2012: 329 (315 in May 2012)
  - Daily: 257
  - Will call/Routine: 72
- Total Submitter Accounts: 691 (672 in May 2012)

Laboratory Courier Service Map



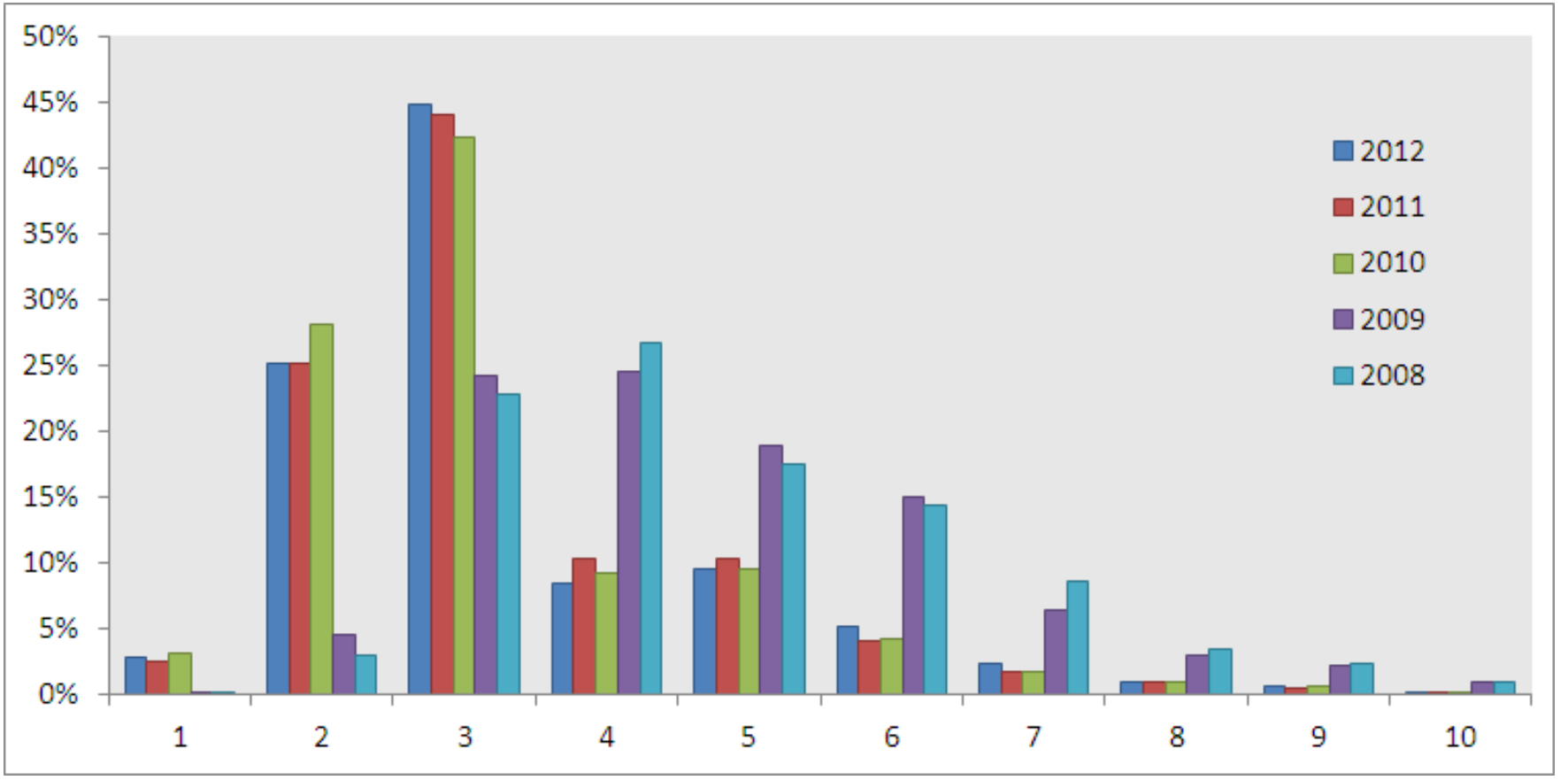
Courier Pilot Project

- Type of specimens: Texas Health Steps, Newborn Screening, Public Health Specimens (started 11/01/2012)
- Percentage of specimens received via courier between 1/1/12 and 6/31/12:
  - THSteps – 35 %
  - NBS – 53%

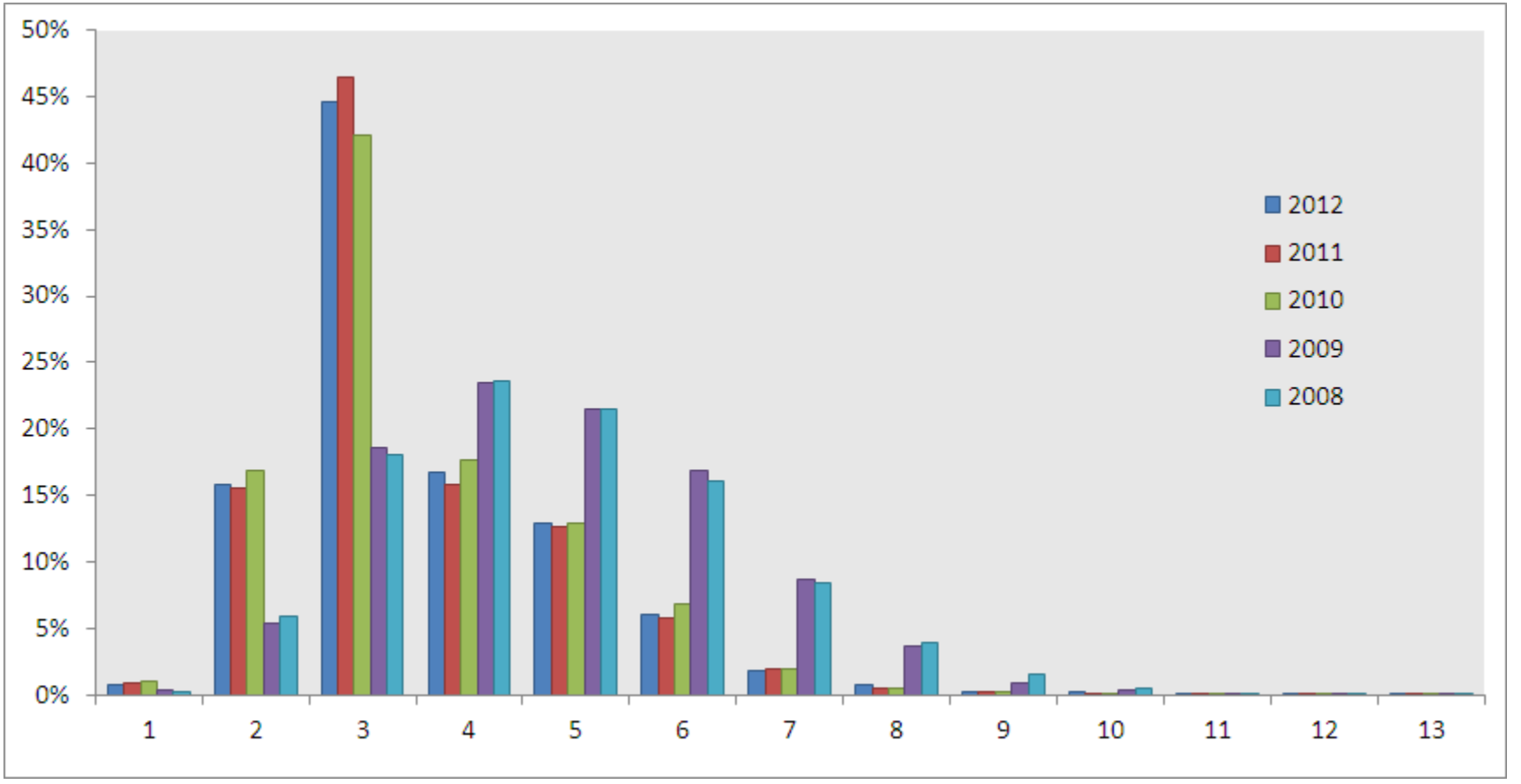
Courier Pilot Project

- Key Success Indicators:
  - Decrease in transit time to the DSHS Laboratory
  - Provide more timely laboratory results by reducing transit times
  - Reduce specimen rejections due to too old for testing and other quality issues
  - Increase submitter satisfaction due to convenience and ease of pick-ups

Transit Time for THSteps Specimens (September)



Transit Time for Newborn Screening Specimens (September)



Clinical Chemistry Updates

- Overview
- Specimen volume
- Efforts continue to reduce specimen rejection

Clinical Chemistry Laboratory

- Texas Health Steps Required Screens
  - Blood Lead – point of care testing effective 12/1/11
  - Total Hemoglobin
  - Hg Electrophoresis – dropped from Schedule, effective 12/1/11
  - Syphilis – testing moved to Serology Lab, effective 6/4/12
  - Hyperlipidemia - Cholesterol
  - Diabetes – Glucose
- Prenatal Screening
  - Hemolytic Disease of the Newborn (HDN) – testing forwarded to ASH, effective 10/16/12

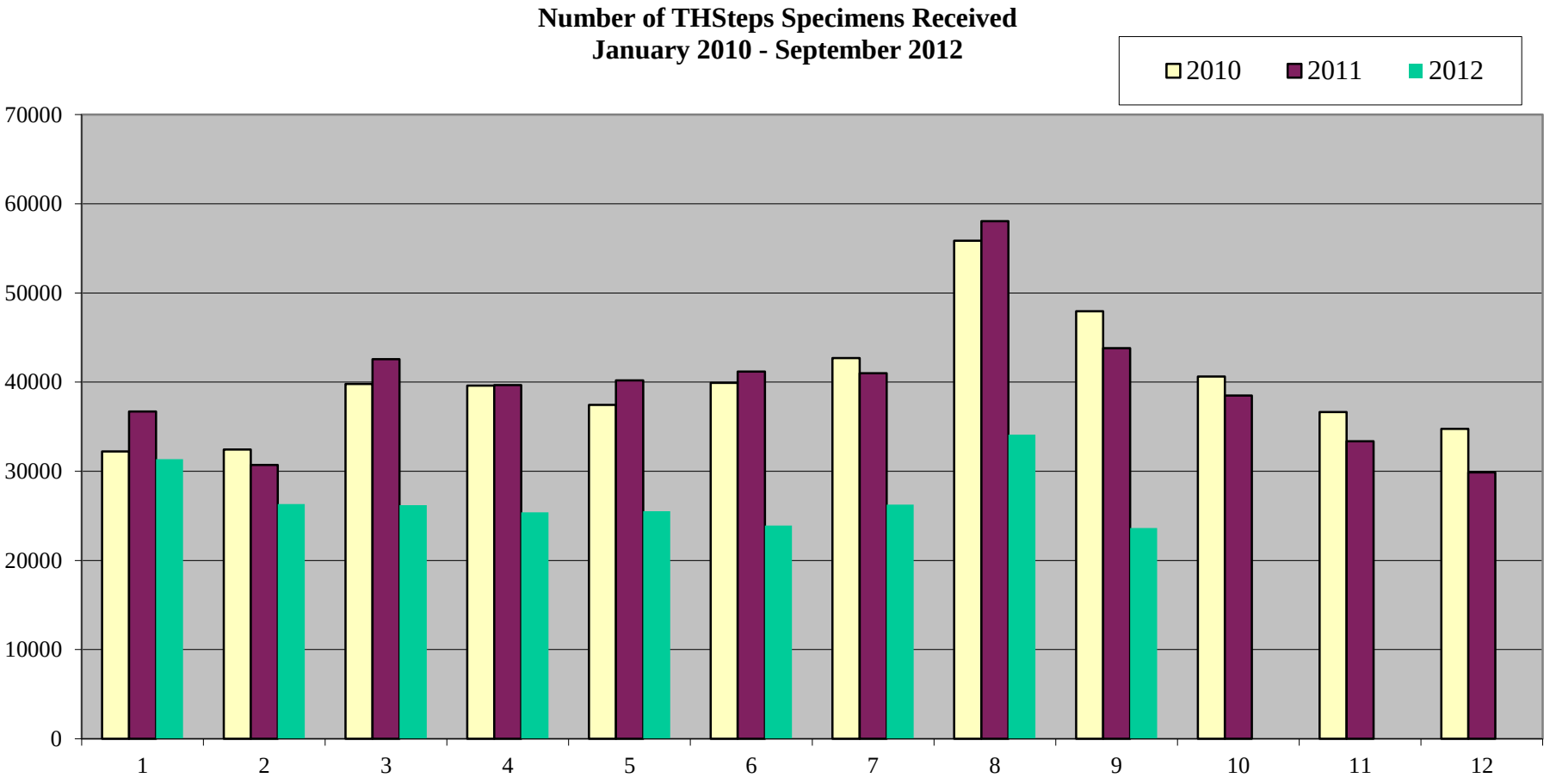
2011 Clinical Chemistry Volume

- Hemoglobin, Lead, Hb Types, RPR = 460,039
- Glucose = 3364
- Hyperlipidemia = 5375
- HDN = 7747
- Total for all testing performed in Clinical Chemistry = 476,525

Clinical Chemistry Volume

- Jan-Sept 2011 vs. Jan-Sept 2012
  - Lead
    - 2011 Lead orders = 247,049
    - 2012 Lead orders = 163,120 — 34% decrease
  - Hemoglobin
    - 2011 Hemoglobin orders = 296,689
    - 2012 Hemoglobin orders = 198,137 — 33% decrease
  - Hemoglobin electrophoresis
    - 2011 orders = 38,397
    - 2012 orders = 16,514 — 57% decrease

THSteps Test Volume: Specimens Received for Hemoglobin/Lead



Jan.-Sept. 2011: 373,948

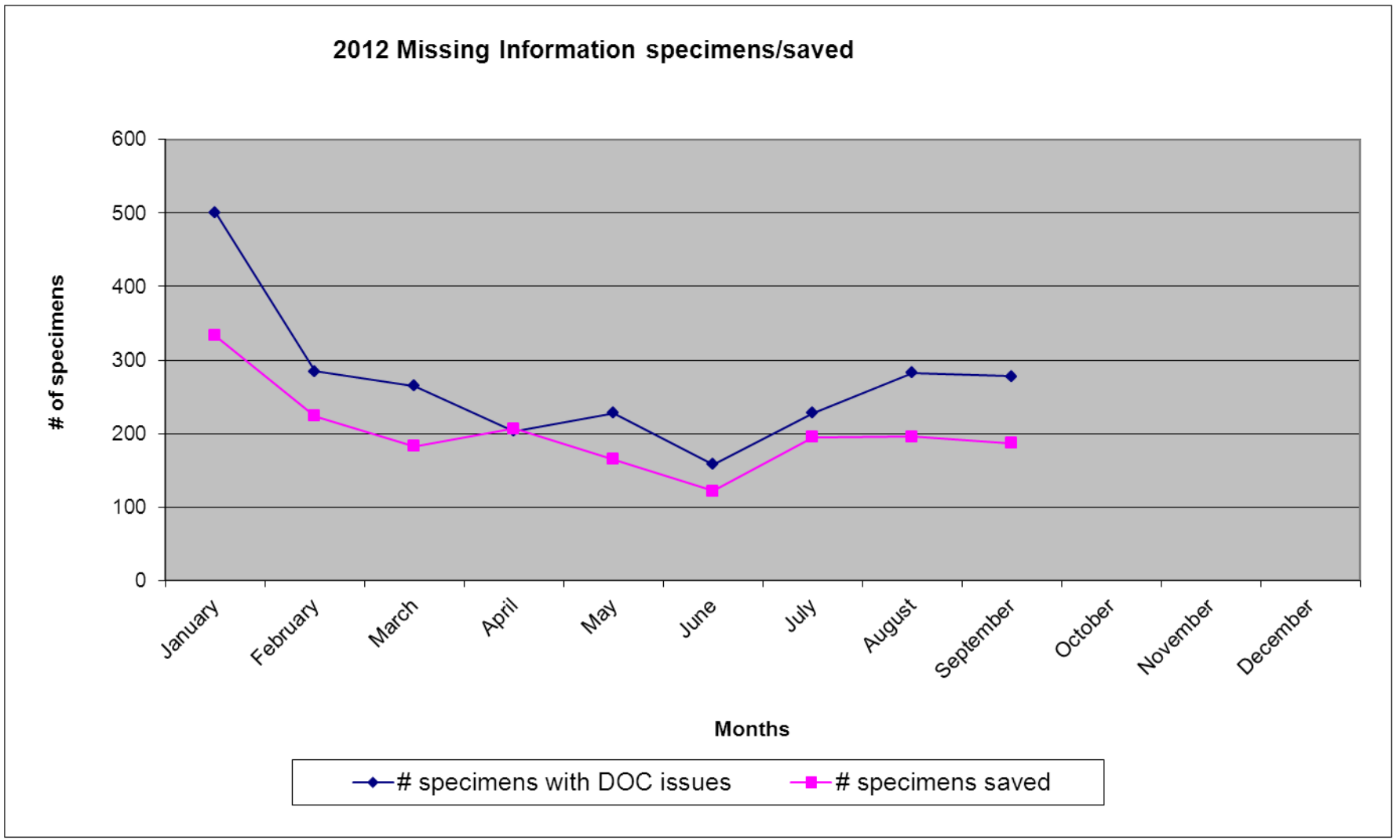
Jan.-Sept. 2012: 242,783

Jan.-Sept. 2012:
35% decrease over 2011

Efforts to Reduce Specimen Rejections

- Calls/faxes to collect information required for testing
- Calls/faxes to provide notification/training on unsatisfactory specimens
- Public Health Performance Measures Project
  - Review of current report card
    - provides a huge amount of information - hard to interpret
    - provided quarterly - often too late for provider to correct issues in a timely manner
    - Process to prepare and mail reports is time-consuming and costly
  - New report card (coming in early 2013)
    - provided monthly with top three rejections so that changes can be made in a more timely manner
    - provided electronically which eliminates costly mailing process

Clinical Chemistry: Date of Collection Issues



1812 specimens saved Jan. – Sept. 2012 76% success rate

Newborn Screening Updates

- Overview
- HB411 Changes
- SCID Screening Implementation
- Special Projects

Newborn Screening Panel

- Currently screen for 28 disorders
  - Congenital Hypothyroidism
  - Congenital Adrenal Hyperplasia
  - 3 Hemoglobinopathies
  - Galactosemia
  - Biotinidase Deficiency
  - 6 Amino Acid Disorders
  - 5 Fatty Acid Oxidation Disorders
  - 9 Organic Acid Disorders
  - Cystic Fibrosis – added December 1, 2009
- 600-700 cases diagnosed annually

NBS Specimen Volume

- Goal: To test each infant twice:
  - 24 to 48 hours of age &
  - 1 to 2 weeks of age
- 2011: Received ~741,000 specimens
  - ~ 2,400 specimens per day (6 days per week)
  - ~ 5,700 unsatisfactory specimens (0.77%)
- 2012 (Jan. – October):
  - ~619,000 specimens - No change from 2011
  - ~4900 unsatisfactory specimens (0.79%)

Top 5 Unsat Reasons

- Blood did not Soak Through Paper - Incomplete saturation
  - ~230 specimens/month (20% increase from 2011)
- Blood was Caked, Clotted, or Layered onto the Filter Paper (~210 specimens/month)
- Specimen Appears Contaminated or Discolored
  - ~160 specimens/month (20% increase from 2011)
- Specimen Too Old Upon Receipt (~65 specimens/month)
- Blood Did not Completely Fill Specimen Circles(~30 specimens/month)

Unsatisfactory Specimens Web Page

Newborn Screening - Healthcare Provider Resources

- Parent Resources | **Healthcare Provider Resources** | FAQ -
- Laboratory Services Section Home | NBS Home –

Unsatisfactory Specimens

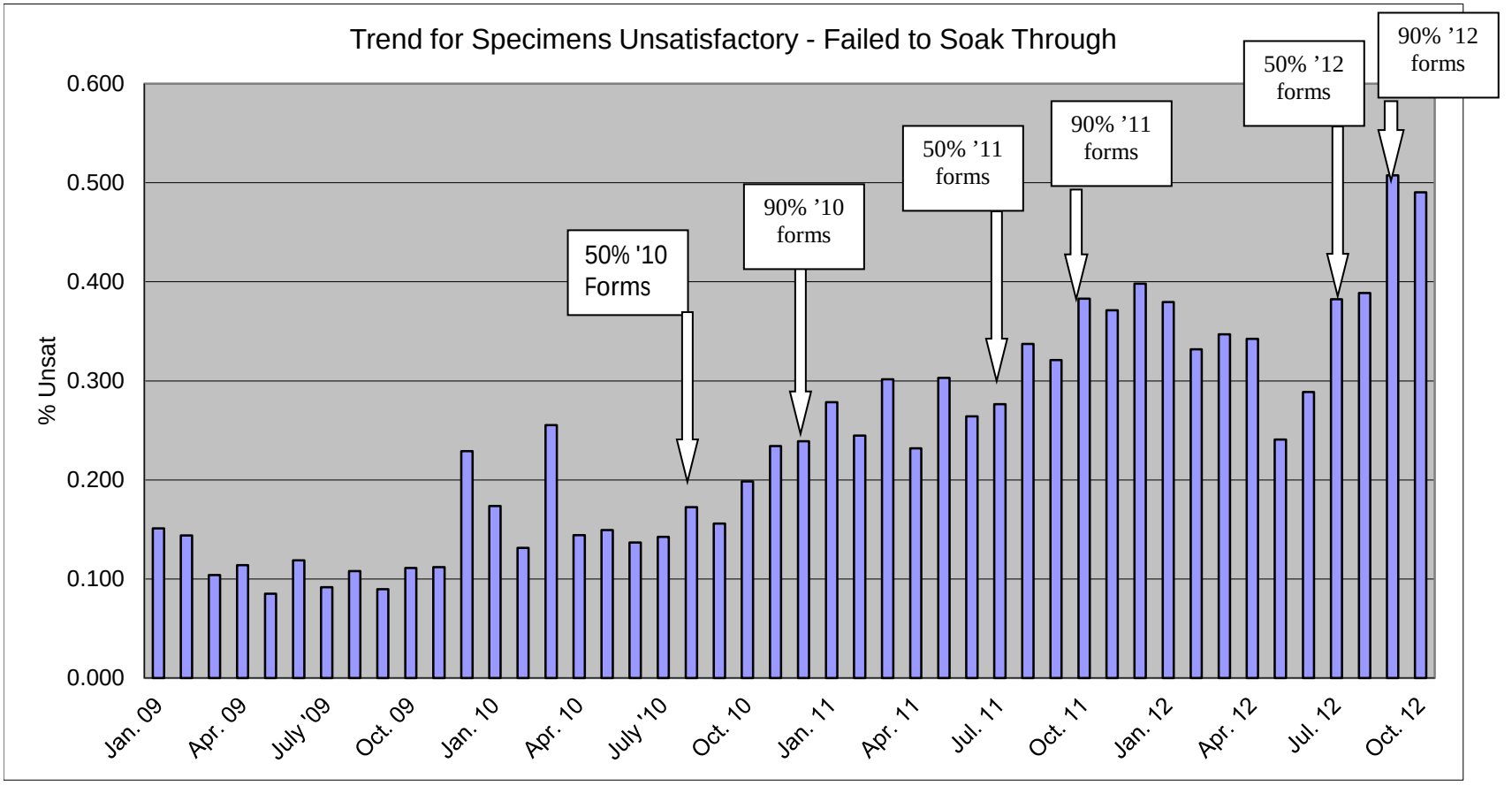
The DSHS Newborn Screening Laboratory reports unsatisfactory specimen results to the submitting facility **ONLY**. It is the submitting facility's responsibility to ensure than an adequate specimen is re-collected.

See below for information on, examples of, and tips for avoiding the most common unsatisfactory qualities reported by the DSHS NBS laboratory.

- **Blood did not Completely Fill Specimen Circles.**
  Examples / Tips to Avoid
- **Blood did not Soak Through Paper - Incomplete saturation.** – This is the most common reason for unsatisfactory NBS specimens.
  Examples / Tips to Avoid
- **Filter paper is scratched from the possible use of capillary tubes.** – The Clinical and Laboratory Standards Institute and the DSHS NBS Laboratory recommend that the preferred method for collection of NBS specimens is by direct application from a puncture on the baby's heel. The use of capillary tubes as part of specimen collection should only occur as a last resort. It is imperative to note that EDTA, Citrate Anticoagulant, and heparin have been shown to interfere with NBS tests.
  Examples

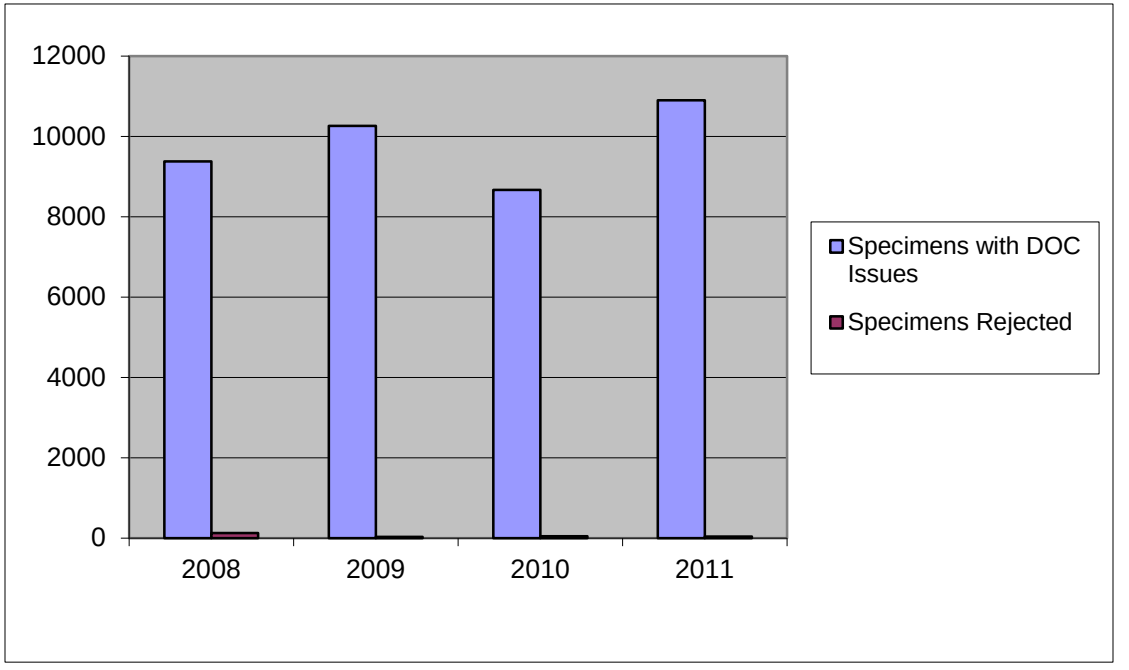
Specimen Quality Issues

Long Term Summary / Lot to Lot Comparison of Saturation Issues



Date of Collection Issues

- Specimens received/processed to prevent rejection due to missing or improper DOB/DOC
- Over 9800 specimens per year received with missing or invalid DOC



- 99.6% save success rate
- 1200+ staff hours per year dedicated to saving specimens with missing, invalid or illegible dates of collection

HB411 Changes

- HB 411 (82nd Legislative Session) became law in June 2011 with parts that are effective June 1, 2012
  - Codified portions of the DSHS policy 'Management of NBS Specimens and Data' in regards to review and approval requirements
  - Changes previous opt-out for residual uses to an opt-in system for external research uses
    - Otherwise, specimen is destroyed within two years of receipt at DSHS
  - Made adjustments to statutorily allowable uses (e.g. for internal QA/QC uses)

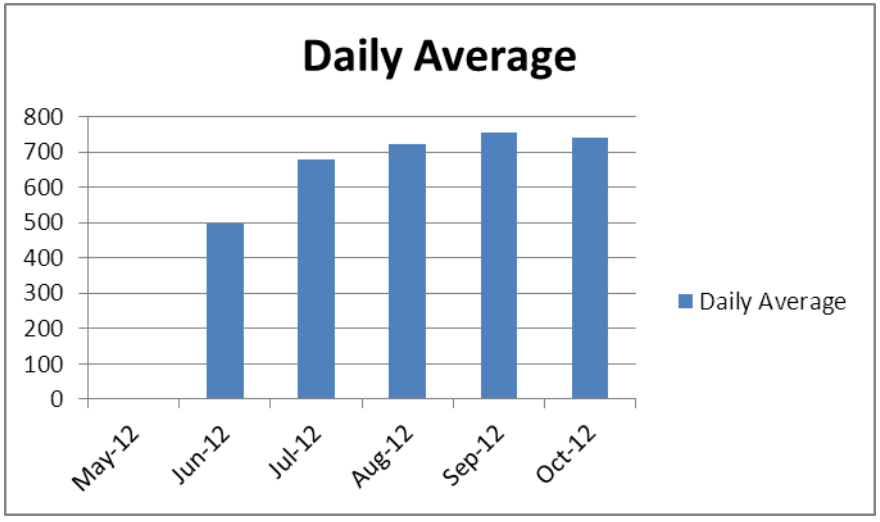
HB411 Implementation

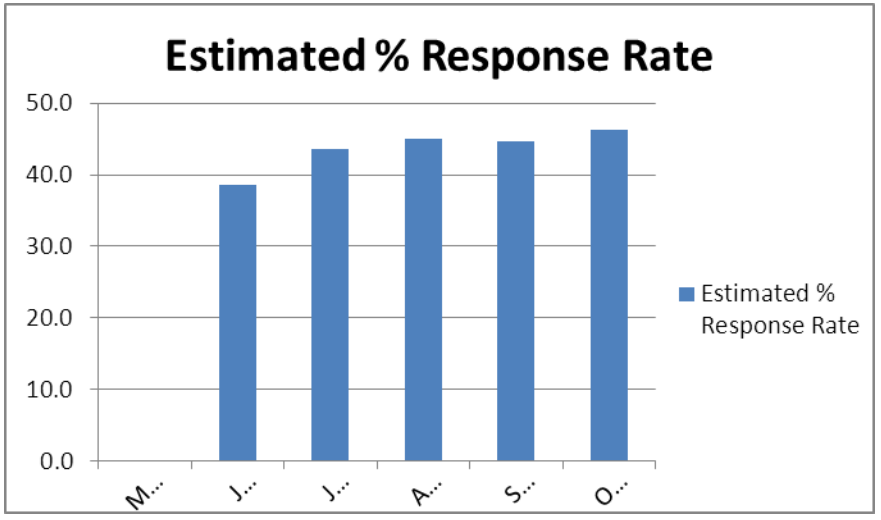
- 2012 specimen collection kit
  - Update Parent Information sheet
  - Parent Decision Form
- Educational efforts:
  - Staged notifications
  - Webinar and face to face educational sessions
  - Video, online module, brochure
  - Update web site
  - Targeted education to providers that do not appear to be completing responsibilities

Parent Decision Forms Stats

Month	Decision Forms Received	Daily Average	Estimated % Response Rate	% YES	% NO	% Invalid
Jun – Oct 2012	49473	675	42.6	70.7	25.8	3.5

Estimated % Response = (# of Decision forms received* 1.54 specimens per form) / # of Specimens Received)





SCID NBS Screening

- Addition of SCID to NBS panel approved by Commissioner Lakey and Executive Commissioner Suehs in March 2012
- Implementation process
  - Building retrofit
  - Personnel and training
  - Purchasing
  - Instrument installation and laboratory set-up
  - Method/instrument validation and scale-up
  - LIMS modification and other IT issues
  - HL7 sites
  - Communication plan and educational efforts

L213 – Construction Phase

L213 – Construction Phase

L213 at 50% Completion

L213 as of 11/09/2012

L213 as of 11/09/2012

L 213 as of 11/09/2012

L213 as of 11/09/2012

SCID NBS Screening

- Implementation status
  - Building retrofit – 99% complete
  - Personnel and training – 1 lab staff and 1 nurse pending
  - Purchasing – 99% complete
  - Instrument installation and laboratory set-up – complete except enclosures and a defective cytomat
  - Method/instrument validation and scale-up
  - LIMS modification and other IT issues
  - HL7 sites
  - Communication plan and educational efforts

Special Projects

- Routine Second Screen Study
  - Purpose: To evaluate evidence regarding the use of second screens for identification of hypothyroidism and congenital adrenal hyperplasia cases
  - Status: Preliminary data available, further data analysis in progress
    - 11.63% of Congenital Hypothyroidism cases were identified on the 2nd screens
    - 37.50% of Congenital Adrenal Hyperplasia cases were identified on the 2nd screens
    - Incidence rates are still pending

Special Projects

- Development of Second Tier Assay for CAH
  - Purpose: To perform a steroid profile (5 analytes) by LC-MS/MS to reduce false positive rate
  - Status: Validation and 3 month pilot study in progress
    - Testing all positive samples reported by initial screen
- New Newborn Screening Report Card format (coming in early 2013)

Report Card: Original Format

2008 NEWBORN SCREENING REPORT CARD WITH SCREEN INFORMATION

Submitter ID:

Submitter NPI:

Submitter Name:

SUBMITTER STATISTICS:

Submitter Category: HIGH Volume *

Specimen Quality: 73 of 592 Unsatisfactory (12.33%)

Transit Time: 70 of 592 Rejected

Your Rank for Specimen Quality: 114 of 114

				UNSATISFACTORY SPECIMEN QUALITY (One unsatisfactory specimen may have up to 25 unsatisfactory codes.)																			*INFANT'S AGE AT TIME OF SCREEN*						*TIME FROM COLLECTION TO RECEIPT*							
Month	**TOTAL SPECIMENS SUBMITTED**	**TOTAL NUMBER OF UNSATISFACTORY SPECIMENS**	**UNSATISFACTORY RATIO**	SPECIMEN CIRCLES	BLOOD DID NOT COMPLETELY FILL	BLOOD DID NOT SOAK THROUGH PAPER - INCOMPLETE SATURATION	BLOOD DID NOT SOAK THROUGH PAPER - POSSIBLE USE OF CAPILLARY TUBES	FILTER PAPER IS SOILED/STAINED FROM THE OTHER SIDE	SPECIMEN APPEARED CONTAMINATED OR DISCOLORED	BLOOD WAS DRIED, CLOTTED, OR LAYERED ONTO THE FILTER PAPER	BLOOD WAS DRIED, CLOTTED, OR CONTAMINATED	EDTA OR OTHER ANTICOAGULANT	ASSAY INTERFERENCE DUE TO	ASSAY INTERFERENCE	FILTER PAPER	INCOMPLETE ELUTION OF BLOOD FROM FILTER PAPER	PATIENT INFORMATION INCOMPLETE OR INVALID	INFORMATION FORM DOES NOT MATCH NUMBER OF SPECIMENS SUBMITTED	SERIAL NUMBER ON PATIENT	SPECIMEN TOO OLD UPON RECEIPT	UNABLE TO ANALYZE SPECIMEN DUE TO LABORATORY ACCIDENT	NO BLOOD SAMPLES RECEIVED WITH REQUEST FORM	SPECIMEN SUBMITTED ON IMPROPER COLLECTION FORM	COLLECTION FORM	SPECIMEN SUBMITTED ON DUPLICATE	SPECIMEN RESULTS INCONSISTENT	DRYING OF SPECIMEN COLLECTION	SERUM SEPARATION DUE TO IMPROPER	SPECIMEN DAMAGED DURING TRANSPORT TO LABORATORY	**TOTAL NUMBER OF UNSATISFACTORY CODES**	SCREENED ON DAY: LESS THAN 1 DAY	SCREENED ON DAY: 1-2 (1st Screen Goal)	SCREENED ON DAY: 3-6	SCREENED ON DAY: 7-14 (2nd Screen Goal)	SCREENED ON DAY: 15 OR MORE	SCREENED ON DAY: UNKNOWN	RECEIVED ON DAY: 1-3 (Great)	RECEIVED ON DAY: 4-5 (Good)	RECEIVED ON DAY: 6-7 (Fair)	RECEIVED ON DAY: 8-9 (Needs Improvement)	RECEIVED ON DAY: 10-13 (Needs Improvement)	RECEIVED ON DAY: 14 OR MORE (Rejected)	RECEIVED: MISSING DATE OF COLLECTION (Rejected)	**AVERAGE TRANSIT TIME**
01 - JAN	190	9	4.74%	0	0	0	0	0	0	0	0	0	0	0	0	0	7	0	0	0	2	0	0	0	9	2	157	8	2	21	0	3	48	68	43	21	7	0	7.1
02 - FEB	90	7	7.78%	0	0	0	0	0	0	0	0	0	0	0	0	0	7	0	0	0	0	0	0	0	7	1	67	5	7	10	0	1	30	27	1	24	7	0	7.9
03 - MAR	312	57	18.27%	0	0	0	0	0	0	0	0	0	0	0	0	2	0	55	0	0	0	0	0	0	57	5	248	15	11	31	2	64	84	49	23	36	54	2	7.3
Totals:	592	73	12.33%	0	0	0	0	0	0	0	0	0	0	0	0	2	0	69	0	0	0	2	0	0	0	73	8	472	28	20	62	2	68	162	144	67	81	68	2	7.4
																																11.49%	27.36%	24.32%	11.32%	13.68%	11.49%	0.34%	
Category Totals:	112,867	563	0.50%																							**995**	**73,898**	**2677**	**21,079**	**14,220**	**30**	**23,177**	**45,899**	**33,065**	**8,313**	**1,982**	**311**	**30**	**5.2**
Totals for All Submitters:	196,388	1,612	0.82%																							1,331	94,234	4,405	50,868	45,832	254	34,319	85,243	57,624	14,788	3,590	696	254	5.3

* Submitter Category Volume is determined by average number of monthly submissions:

HIGH : 150 or more
MEDIUM : 21 - 149
LOW : 20 or less

DSHS Laboratory Services Section
P. O. Box 149347, Austin, TX 78714-9347 ***1-888-963-7111 x6030***

Report Card:
New Format

Texas Department of State Health Services
LABORATORY SERVICES SECTION

Mailing Address:
PO BOX 149347
AUSTIN, TEXAS 78714-9347
1-888-963-7111 ext. 7333
www.dshs.state.tx.us

Newborn Screening (NBS) Report Card - Specimen Submission

Report Date December 31, 2010
Provider Name:
Address:

Provider ID:

Performance Period: November 01, 2010 - November 30, 2010

Provider Submission Volume	Total
Number of NBS specimens submitted	30
Number of initial screen NBS specimens submitted (e.g. Birth to 7 days old)	15
Number of second screen NBS specimens submitted (e.g. 7 days or older)	15

Specimens Unsuitable for Testing

	Count	Percent	State Average	Goal
Total number of specimens with quality issues	0	0%	1%	0%
Specimens that are unsatisfactory to test for any of the disorders	0	0%	<1 %	0%
Specimens for which results can be reported for some but not all disorders	0	0%	<1 %	0%

There were no quality issues this reporting period for your facility.

Timing on Initial NBS Specimen Collection

	Count	Percent	State Average	Goal
Goal: Collected between 24 and 48 hours	15	50%	45%	100%
Collected too early: < 24 hours of age	0	0%	5%	0%
Collected late: >48 hours of age	15	50%	50%	0%

Specimen Transit Time from Collection to State Laboratory

	Count	Percent	State Average	Goal
Goal: Received by state laboratory within 72 hrs from collection	12	40%	56%	100%
Received by state laboratory <24 hrs from collection	0	0%	9%	
Received by state laboratory <48 hrs from collection	2	7%	33%	
Received on day 14 or more - rejected for testing	0	0%	<1 %	0%

Specimen Missing Key Demographic Information

	Count	Percent	State Average	Goal
Goal: Submission of all key demographic information listed below *	28	93%	62%	100%
Missing date of birth	0	0%	<1 %	0%
Missing time of birth	0	0%	22%	0%
Missing date of collection - may result in rejection for testing	0	0%	<1 %	0%
Missing time of collection	0	0%	16%	0%
Missing birth weight	1	3%	5%	0%
Missing physician name	0	0%	10%	0%
Missing physician phone number	1	3%	13%	0%

* Counts may reflect multiple key items missing from the same specimen

END OF REPORT

TEXAS Department of State Health Services

Questions?