

Blood Lead
Regulatory 5-sample CMS-approved Program
Event 2009-1 Summary
Reporting deadline January 26, 2009

The next regulatory event ships: May 11, 2009

This packet contains:

- an evaluation report of results reported by your laboratory for this event
- a cumulative report covering analyte scores over the past three regulatory events
- a statistics report for all methods reported

Please review the reports carefully. Contact us with any questions or comments at (608) 224-6252, or at toxpt@mail.slh.wisc.edu

Important Information:

Performance Data: Result forms were submitted by 566 participants. Satisfactory performance ($\geq 80\%$ analyte score, or 4/5 correct sample results) was achieved by 90% of the participants. By reporting group, this rate was 95% for refereed methods and 89% for LeadCare users. Of the 57 participants with failing scores, 23 were attributed to late reporting of results. An additional 32 laboratories failed to return reports.

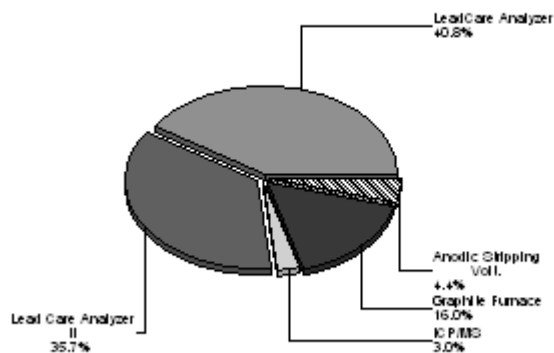
Alpha-numeric results for sample 09PB02: This PT sample contained a lead concentration falling below the limit of quantification for many laboratories. Generally, when a numeric target value is determined for a sample, alpha-numeric results for the sample are scored as satisfactory whenever the alpha-numeric threshold overlaps the acceptable range for the sample. In this specific event however, approximately 82% of the LeadCare II participants reported a result of $<3 \mu\text{g/dL}$, making that the most appropriate target value. Because of system limitations, for evaluation purposes a target value of $2 \mu\text{g/dL}$ has been applied. This value, along with an associated acceptable range of $0-6 \mu\text{g/dL}$ appears on the individual evaluation report for LeadCare II participants. The statistical summary more correctly lists the target value as $<3 \mu\text{g/dL}$ for this reporting group. Please contact program staff with any questions you might have about this sample.

Regulatory Agency Reports: A list of the agencies receiving copies of results for this PT program can be found in the upper left-hand corner of your individual evaluation report. If additions or other changes to the listed agencies are needed you must notify program staff. Participants in the state of California will see two state agencies listed. This is because a second branch within the California Dept. of Public Health requested a separate copy of the PT data.

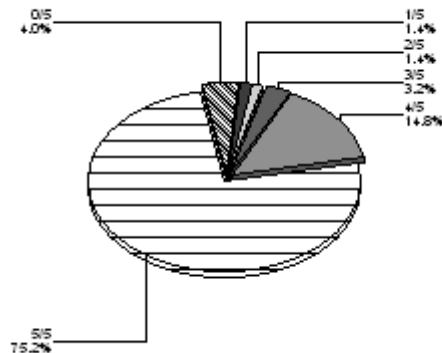
Reporting of Results: Several participants continue to report results incorrectly. **Results are to be reported as whole numbers;** results reported to the $0.1 \mu\text{g/dL}$ may be scored as unacceptable. Also, the greater than ($>$) and less than ($<$) circles should be filled in only when a result falls above or below the limit of quantification, e.g. $>65 \mu\text{g/dL}$ or $<1 \mu\text{g/dL}$. They should not be used for numerical results that have been rounded.

Reporting Deadline CLIA regulations require that PT providers follow strict adherence to reporting deadlines, absent prior notification. Program staff must be contacted prior to the reporting deadline to avoid a zero score for late results. It is the responsibility of the participating laboratory to monitor shipment dates and reporting deadlines. This information can be found on the program website www.toxpt.info. All participants should print and retain a copy of the fax transmission report indicating successful transmission of results.

Analytical Methods



Event Performance



Target and Acceptable Range Information, mg/dL

Group	09PB01	09PB02	09PB03	09PB04	09PB05
Refereed Methods					
Target Value	21	1	15	29	9
Accepted Result	17-25	0-5	11-19	25-33	5-13
LeadCare®					
Target Value	25	1	18	35	10
Accepted Result	21-29	0-5	14-22	31-39	6-14
LeadCare® II					
Target Value	27	<3	20	37	12
Accepted Result	23-31	0-6	16-24	33-41	8-16

Method Statistics

Refereed Group	09PB01	09PB02	09PB03	09PB04	09PB05
Referee Laboratories (N=14)					
Mean	20.7	1.2	14.7	28.8	8.8
Standard Deviation	1.5	0.8	1.0	1.4	0.7
Number of Results *	14	14	14	14	14
All Refereed Methods (N=133)					
Mean*	20.5	1.3	14.7	28.7	8.8
Standard Deviation*	1.6	0.8	1.7	2.1	1.2
Participant Results (%Pass)	95	99	97	92	99
Anodic Stripping Voltammetry (N=25)					
Mean*	20.0	1.9	13.5	28.6	7.6
Standard Deviation*	2.2	1.3	1.9	2.2	1.7
Participant Results (%Pass)	96	100	100	92	100
Electrothermal AA (GFAA) (N=91)					
Mean*	20.6	1.2	15.0	28.8	8.9
Standard Deviation*	1.5	0.8	1.4	2.1	1.0
Participant Results (%Pass)	98	99	99	94	100
ICP-MS (N=17)					
Mean*	21.4	1.9	15.7	29.4	9.3
Standard Deviation*	3.2	1.2	2.1	3.6	1.2
Participant Results (%Pass)	88	100	94	82	100

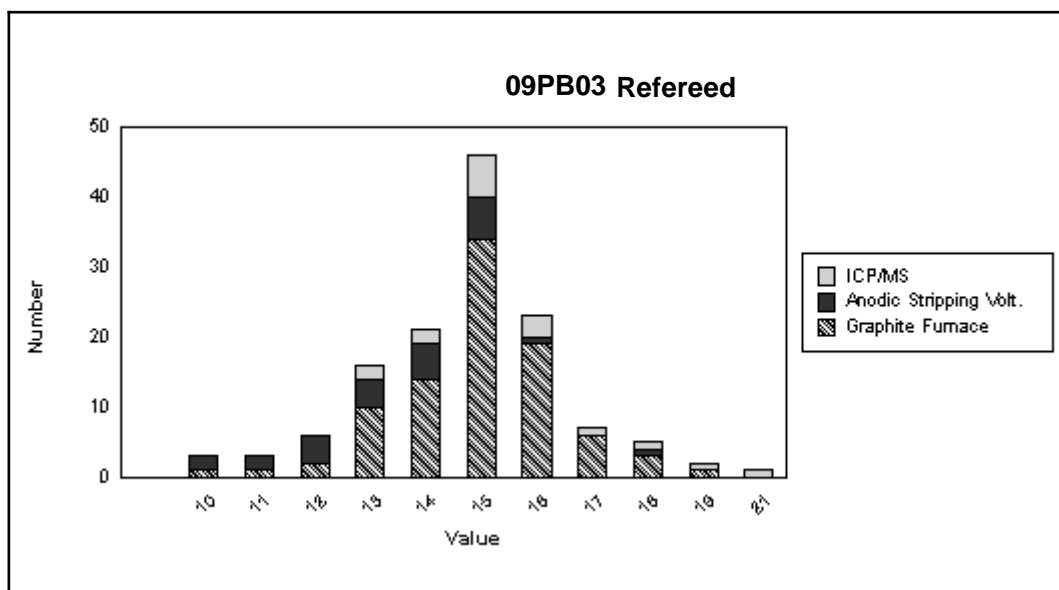
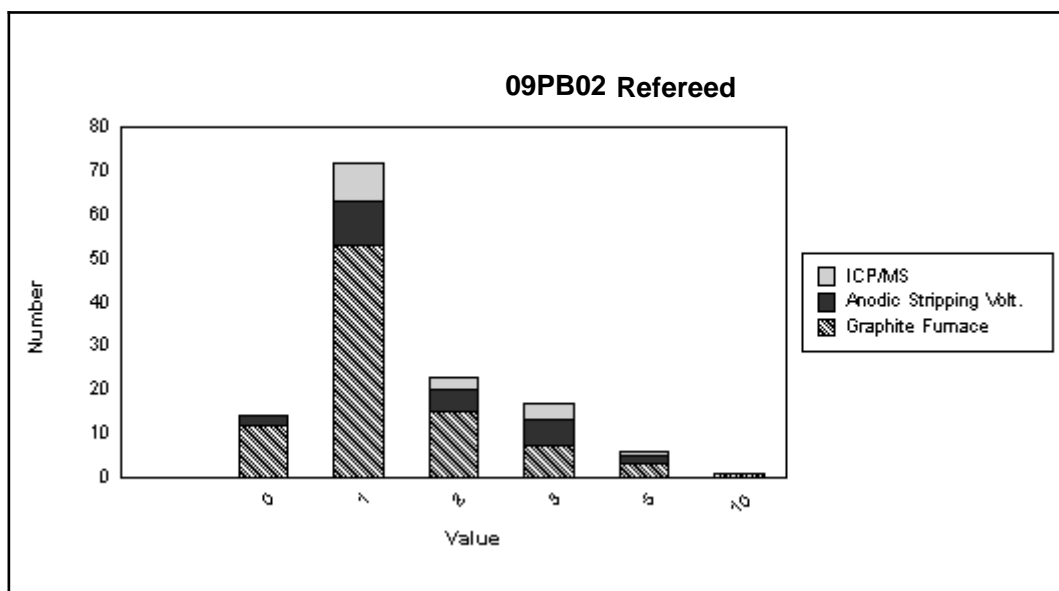
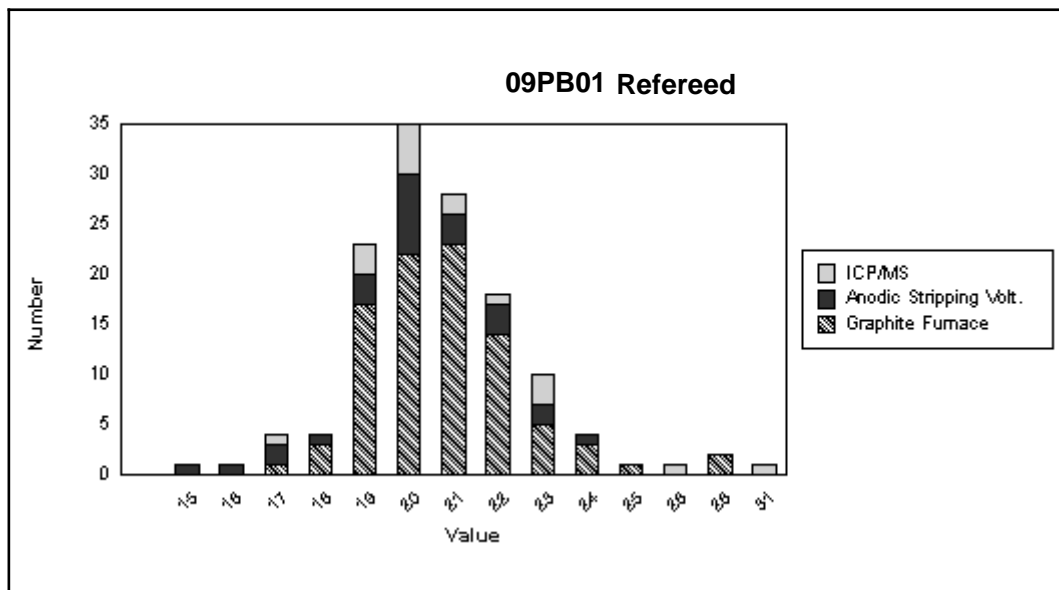
* Statistical outliers and alpha-numeric results (e.g. <X) have been excluded from the calculations

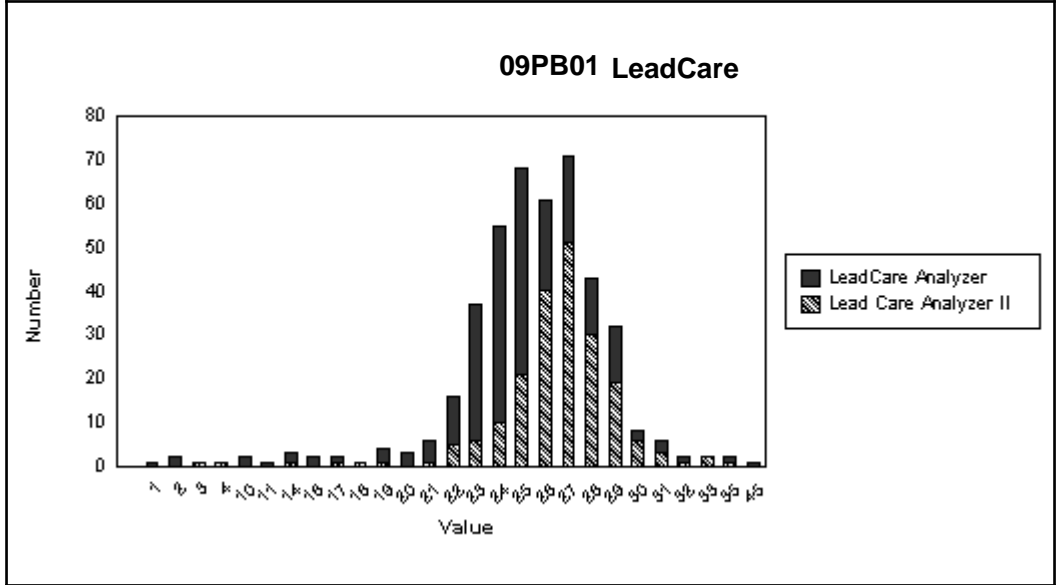
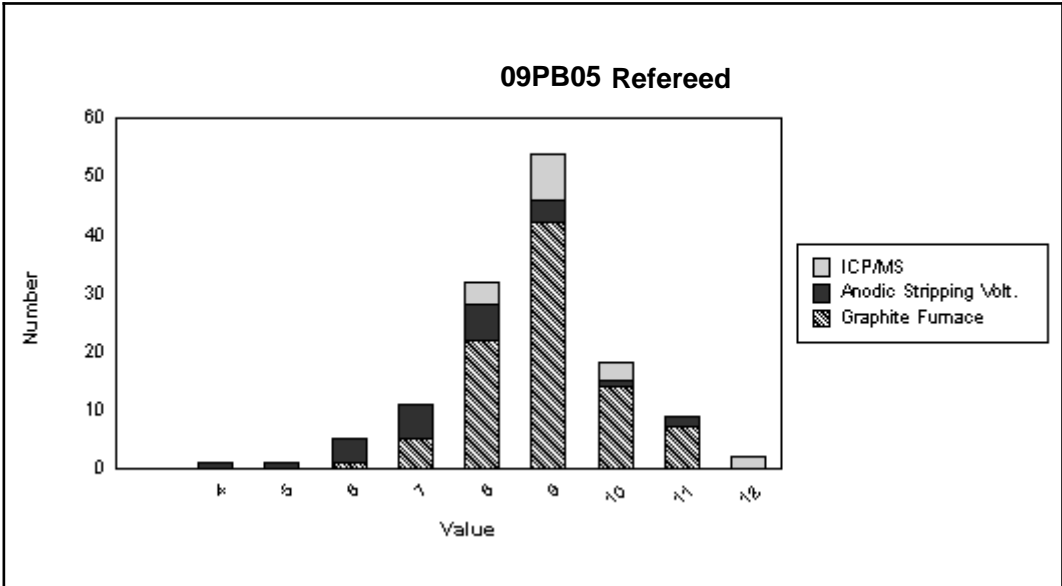
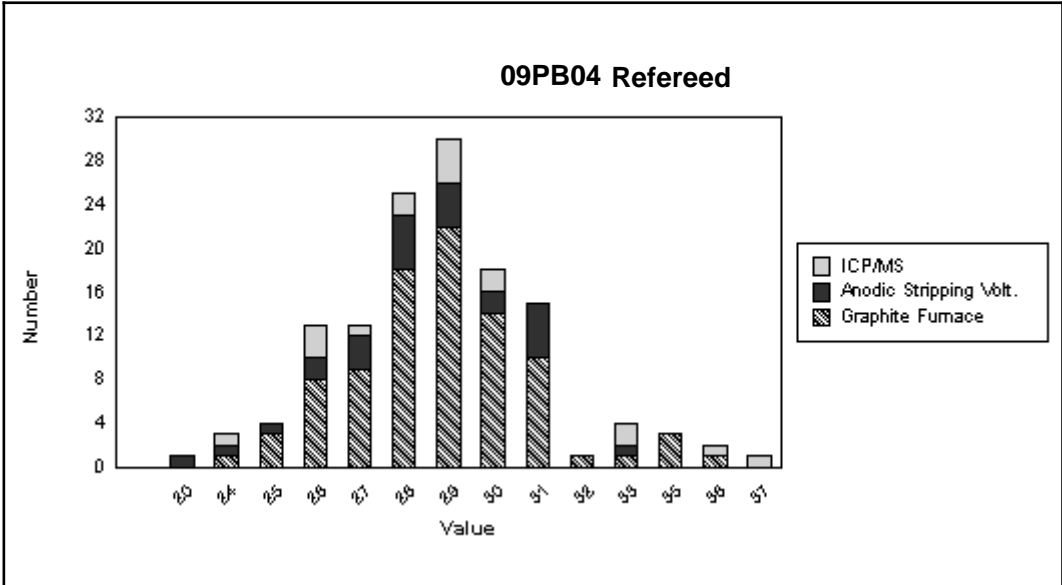
† Lack of statistical group consensus; all results deemed acceptable.

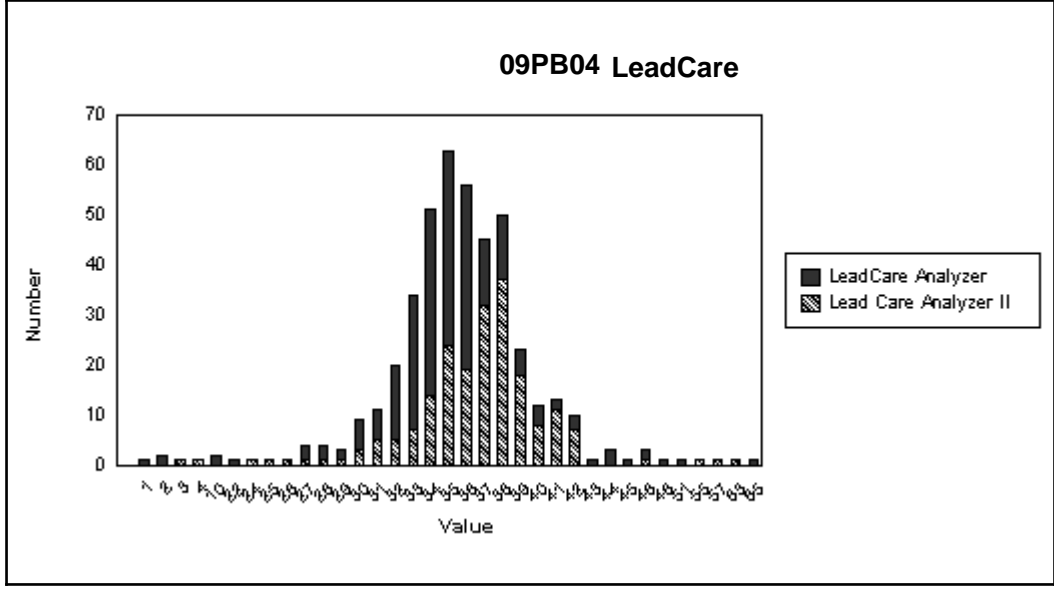
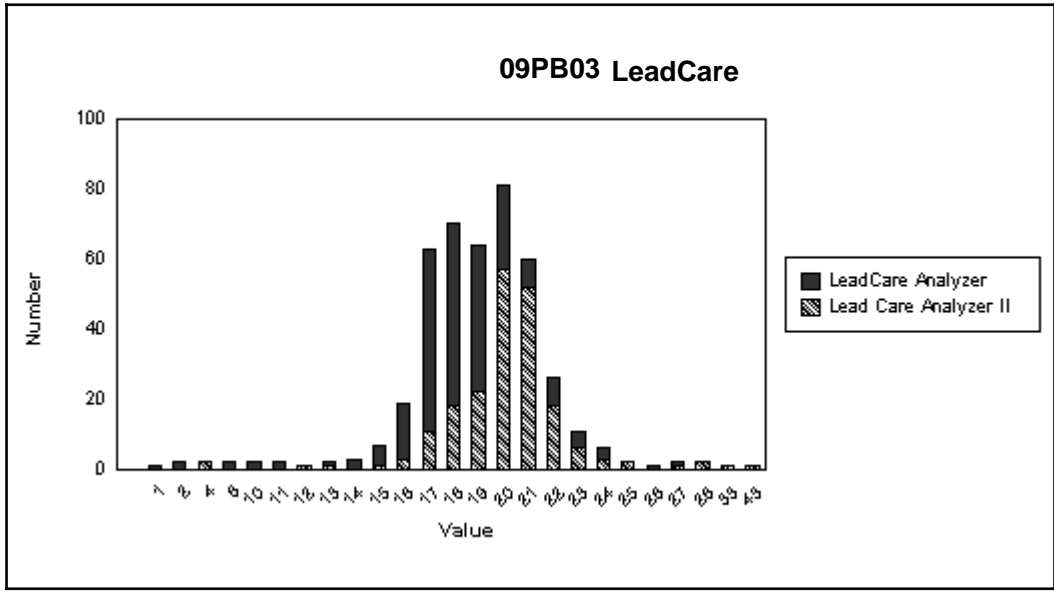
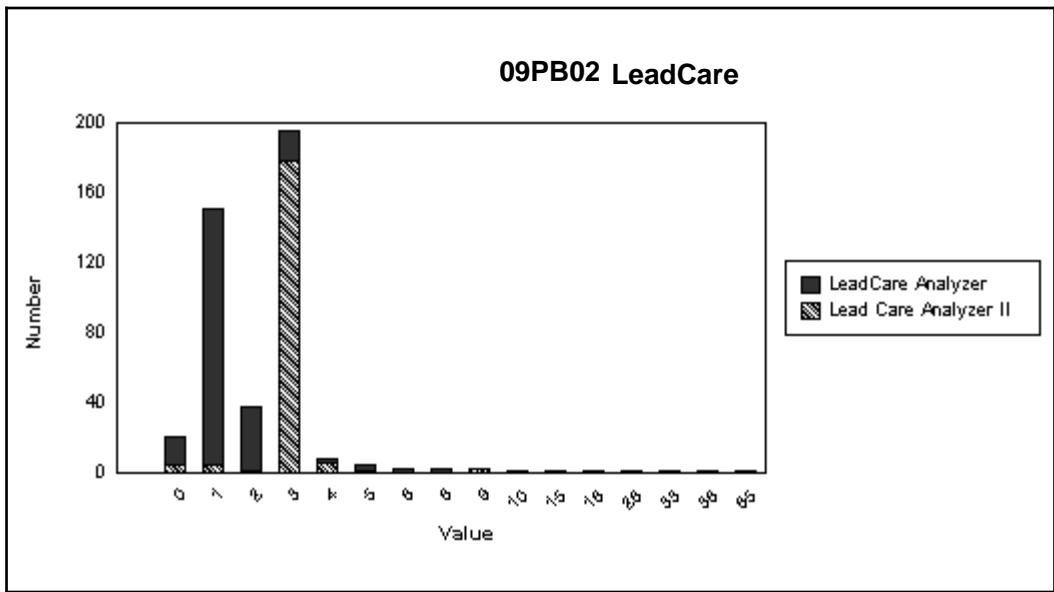
LeadCare® Group	09PB01	09PB02	09PB03	09PB04	09PB05
LeadCare® (N=231)					
Mean*	25.0	1.3	18.3	34.9	10.3
Standard Deviation*	2.3	0.9	1.9	3.0	1.2
Participant Results (%Pass)	89	96	92	83	97
LeadCare® II (N=202)					
Mean*	26.7	<3	20.1	36.7	11.9
Standard Deviation*	2.0	N/A	1.7	2.9	1.5
Participant Results (%Pass)	92	97	94	84	97

* Statistical outliers and alpha-numeric results (e.g. <X) have been excluded from the calculations

† Lack of statistical group consensus; all results deemed acceptable.







09PB05 LeadCare

