

Blood Lead Laboratories A Glimpse at the Future

Impact of Hand Held Technology-a glimpse
at future blood lead reporting issues
September 24, 2002

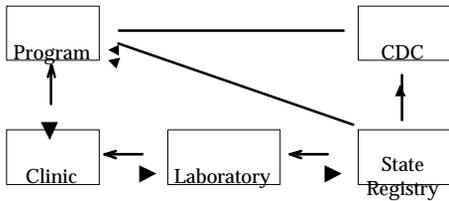
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Division of Laboratory Science



A Blood Lead Laboratory

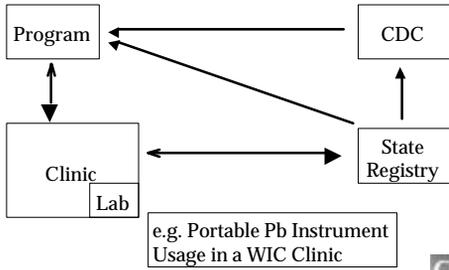


Issues to Consider for the Future Specimen / Data Pathways?

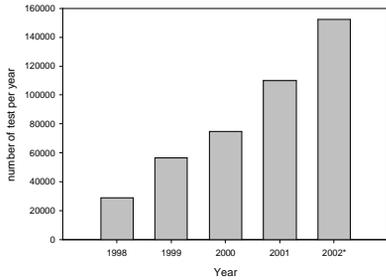


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Issues to Consider for the Future Specimen / Data Pathways?



Estimated Number of LeadCare® Test



Is LeadCare® technology in your state?

AL	3	LA	8	OH	11
AZ	1	MA	27	OK	18
CA	64	MD	3	OR	4
CO	7	ME	2	PA	7
CT	1	MI	13	SD	1
DE	2	MN	4	TN	7
FL	10	MO	6	TX	7
GA	5	MS	7	UT	3
IA	2	NC	2	VA	4
ID	5	NE	1	VT	1
IL	18	NH	1	WA	10
IN	5	NJ	8	WI	6
KS	12	NM	2	WV	2
KY	6	NY	22	WY	1



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Moderate Complexity or Waived?

- FDA defines LeadCare® as Moderately Complex
- CDC has a contract with ESA to convert the Leadcare® instrument to a "waived test".
- Will not be realized for 2-3 years.
- Should build reporting infrastructure now, to overcome reporting issues that may arise.

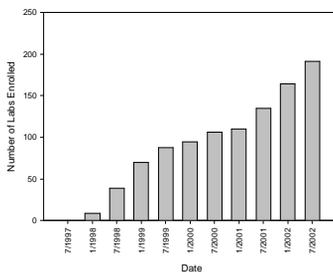


Laboratory Performance How good are results?

- PT = Proficiency Testing: Performance evaluation tool
- Required under CLIA for moderately complex test, not for waived test
- Acceptable vs. exceptional
- Other ways to evaluate: BLLRS, State-level, Private (CAP, JCAHO, COLA)



LeadCare® PT Enrollment

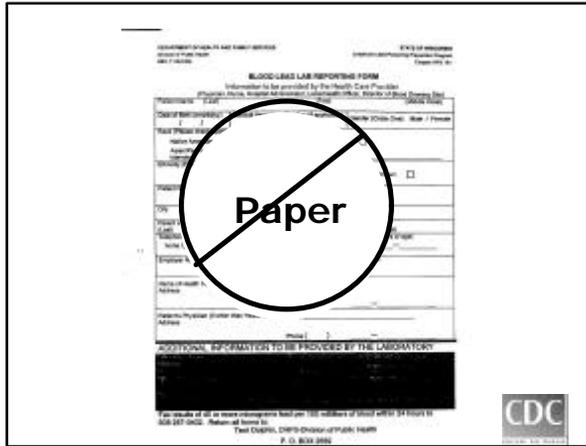


Blood Lead Laboratories A Glimpse at the Future

Blood Pb Laboratory in the Future

- New Analytical Technologies/Methods
- More Point of Care (POC) laboratories
- Reporting (data pathways) may change
 - Submitter?
 - Shift to Electronic
- Lower laboratory costs drives higher follow-up costs





MA Electronic Transfer of PbB Results

ESA has collaborated with MA, and other states, to develop and transfer blood lead reporting software, used specifically for reporting results obtained from the ESA LeadCare® instrument.

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Reporting in the Future

What about state reporting requirements?

- Laboratory-based or Submitter
- Out-of-state considerations
- Lots of demographic info-do not want to duplicate efforts. Submitter has already "entered" this data.



Additional Issues to Consider

- Certifications
- Performance
- Collection materials
- Shipment
- Turnaround & Results
- Reporting
- Environmental specimens "linked"
- Other Metals (e.g. Hg, Cd, etc.)
- Other considerations



Collection Materials

- Prescreened or manufacturer tested
- Collector satisfaction important
- Often provided by laboratory
- May be included in test cost



Blood Lead Laboratories

A Glimpse at the Future

Turnaround & Results in the Future

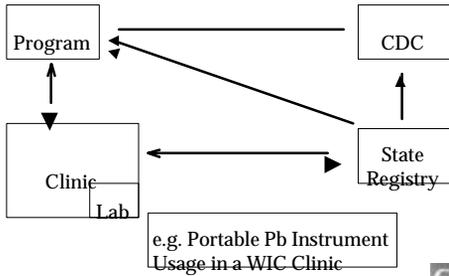
When and how will I get results?

- Turnaround time varies
 - Transit + Testing + Reporting = Total
- Result Reporting formats
 - paper, fax, disk, e-mail(?), modem(?), Internet (FTP, HL7, NEDSS)
 - Electronic transfers need a confirmation step
- Mechanism for urgent specimens e.g. > xx µg/dL
- Electronic Reporting in the Future will speed reporting results



Issues to Consider for the Future

Specimen / Data Pathways?



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