



Evaluation of a Suitable CK-MM Assay Used in Newborn Screening for Duchenne Muscular Dystrophy

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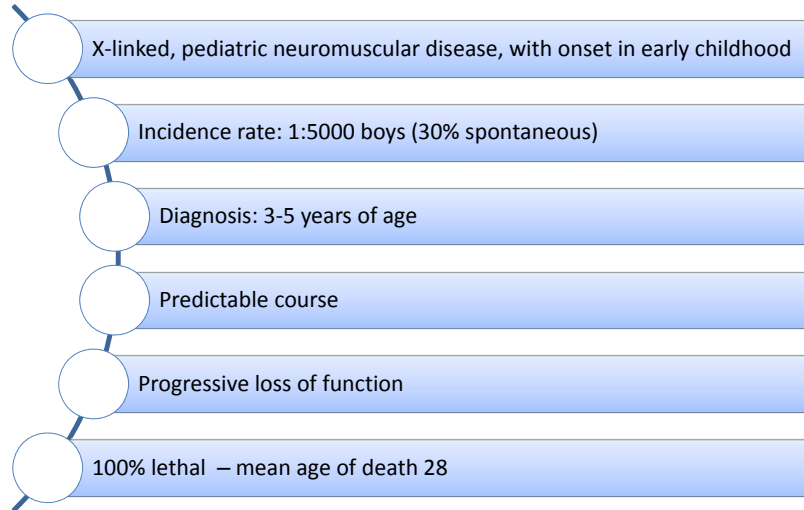


Disclosure

PerkinElmer Provided GSP CK-MM kits

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About Duchenne Muscular Dystrophy



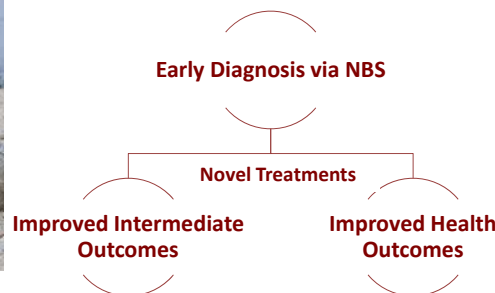
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Parent Project
Muscular Dystrophy
LEADING THE FIGHT TO END DUCHENNE

Duchenne Newborn Screening

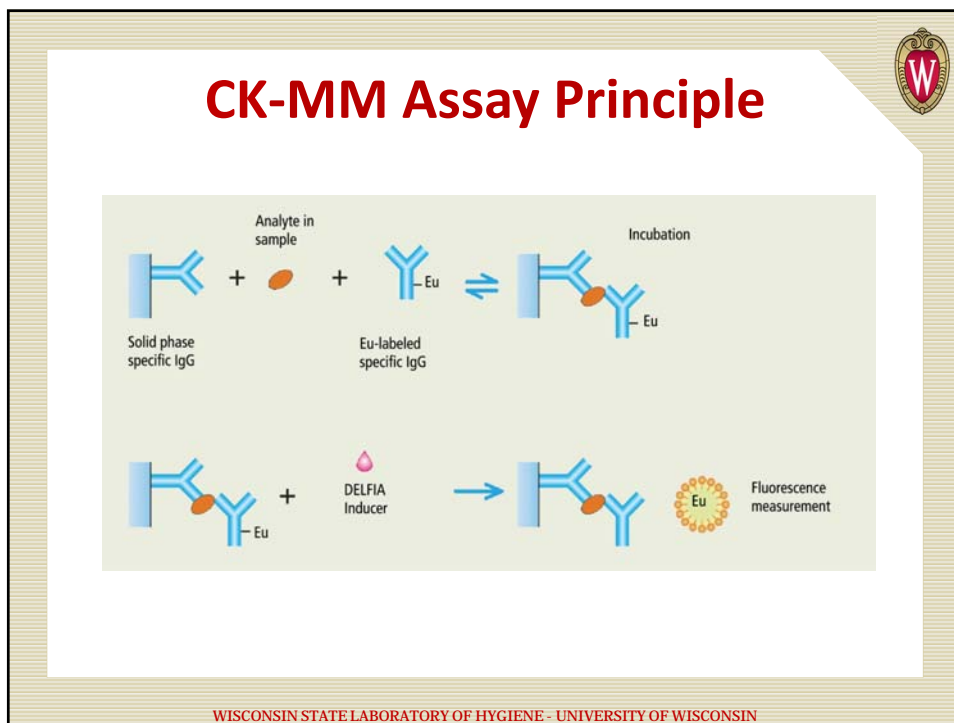
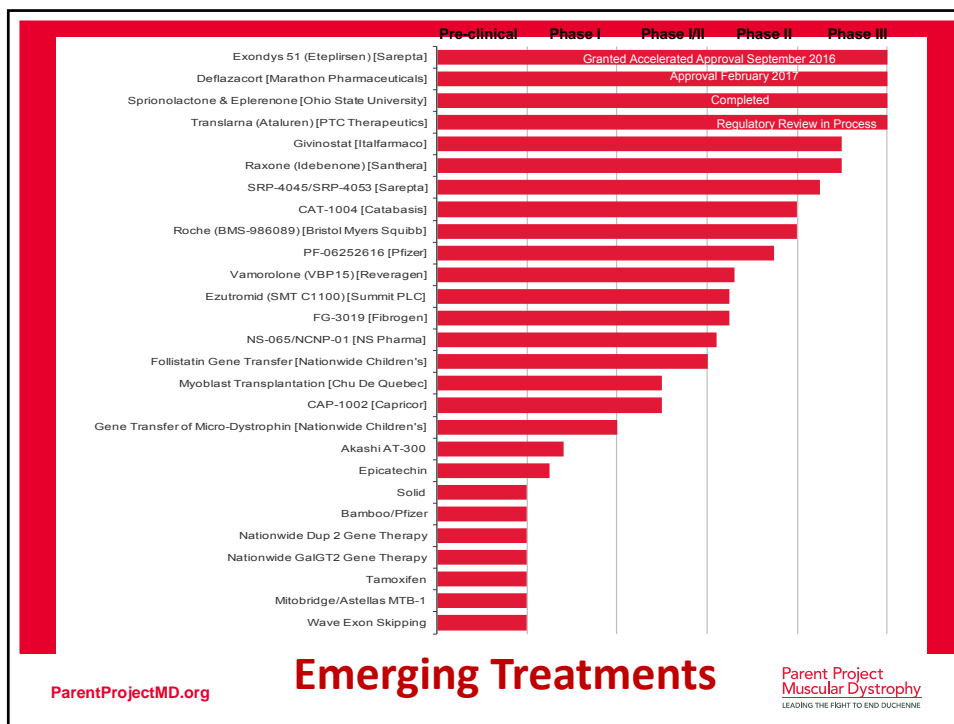



With life-altering treatments on the near horizon, the Duchenne community recognizes the need to identify boys with Duchenne who will derive optimal benefit from these emerging therapies as early as possible – before irreversible fibrosis and muscle deterioration occurs.



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CK-MM Assay Instrument and Kit Components

- **Instrument**
GSP – Genetic Screening Processor
- **Kit Components**
 - Anti-CK-MM Microtitration Strips
 - Calibrators (DBS cassettes)
 - Controls (DBS cassettes)
 - Anti-CK-MM Eu-tracer
 - CK-MM Assay Buffer bottles


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Assay Accuracy

	Control_Low (ng/mL)		Control_Medium (ng/mL)		Control_High (ng/mL)	
	1SD Range (110-158)	2SD Range (86-184)	1SD Range (409-599)	2SD Range (314-694)	1SD Range (1790-2730)	2SD Range (1590-3110)
N	23	2	25	0	25	0


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Assay Within-run Precision Control_Low

	R1	R2	R3	R4	R5	MEAN	SD	CV (%)
Day 1	136	136	153	139	151	143	8.34	5.8
Day 2	145	122	129	124	135	131	9.30	7.1
Day 3	135	132	130	116	123	127.2	7.66	6.0
Day 4	121	121	106	126	139	122.6	11.84	9.7
Day 5	108	122	109	109	110	111.6	5.86	5.2

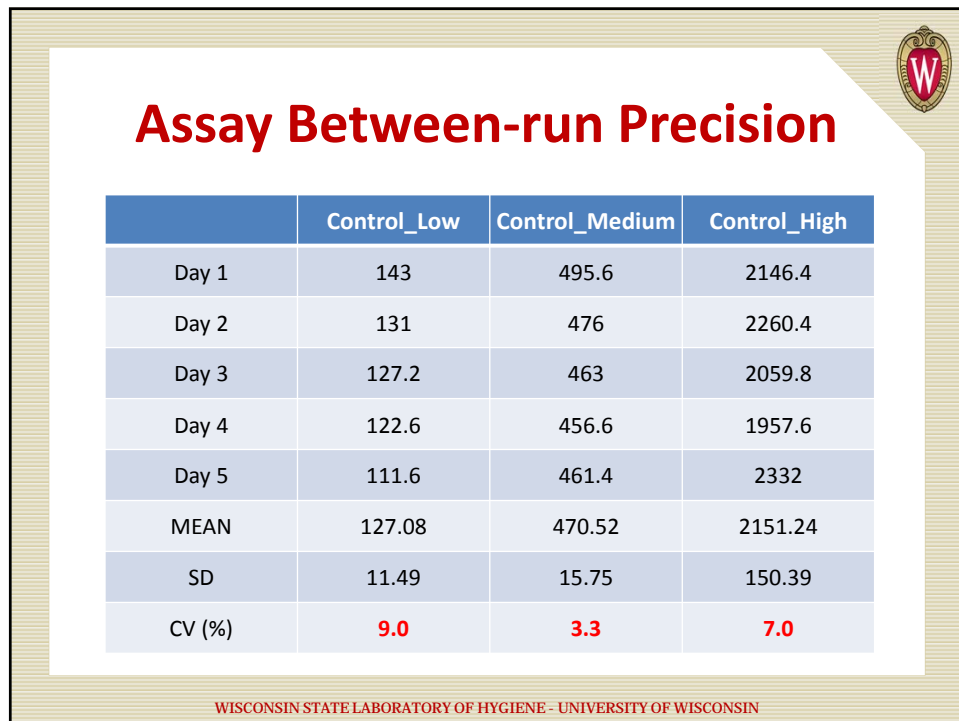
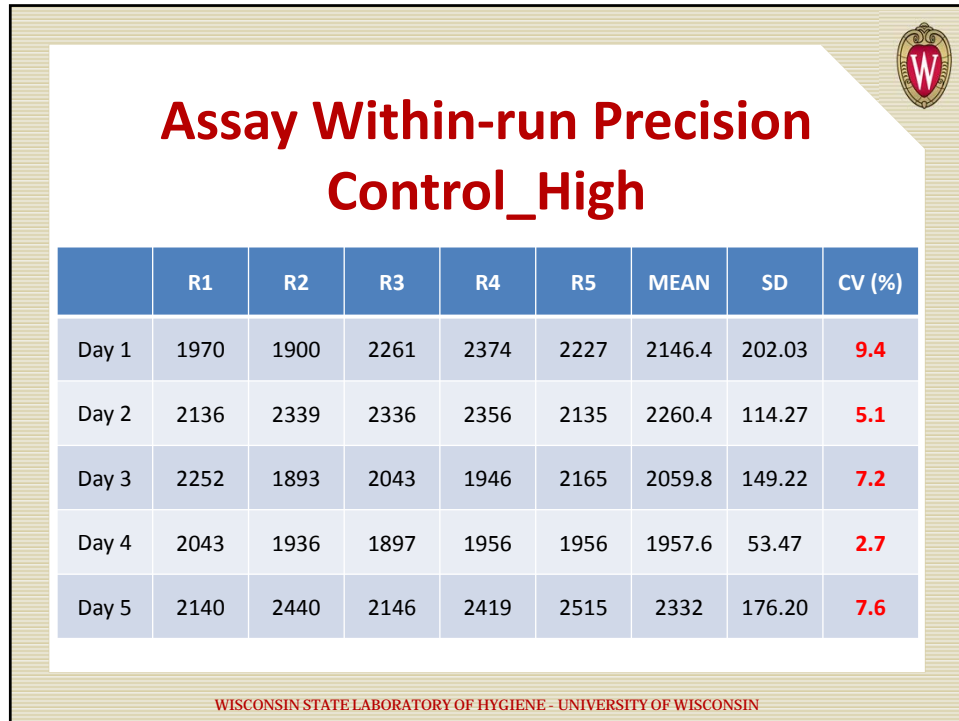
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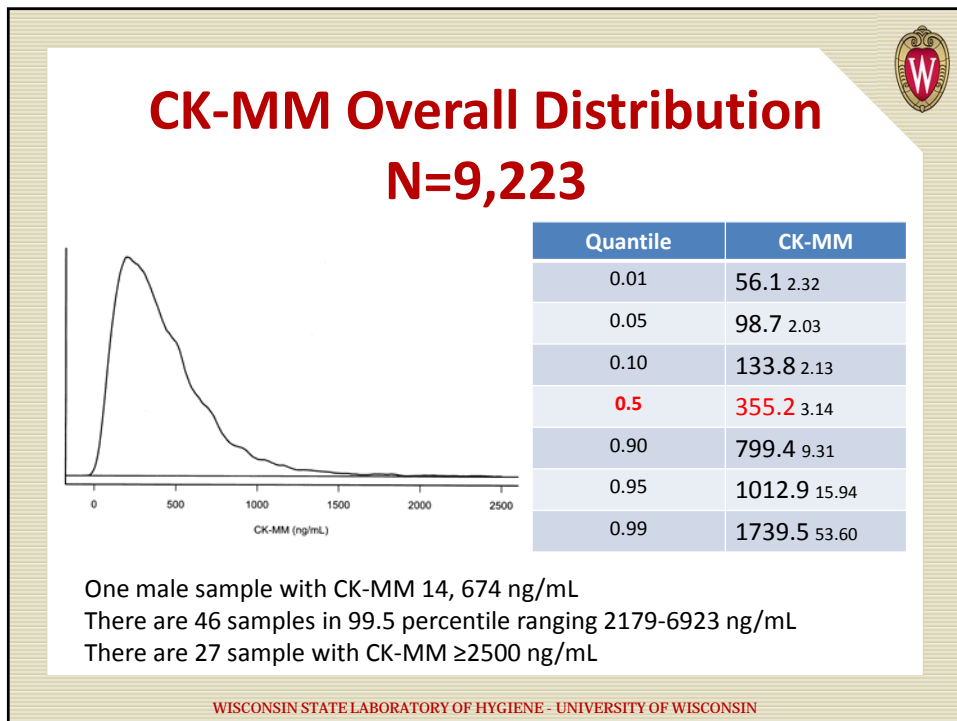
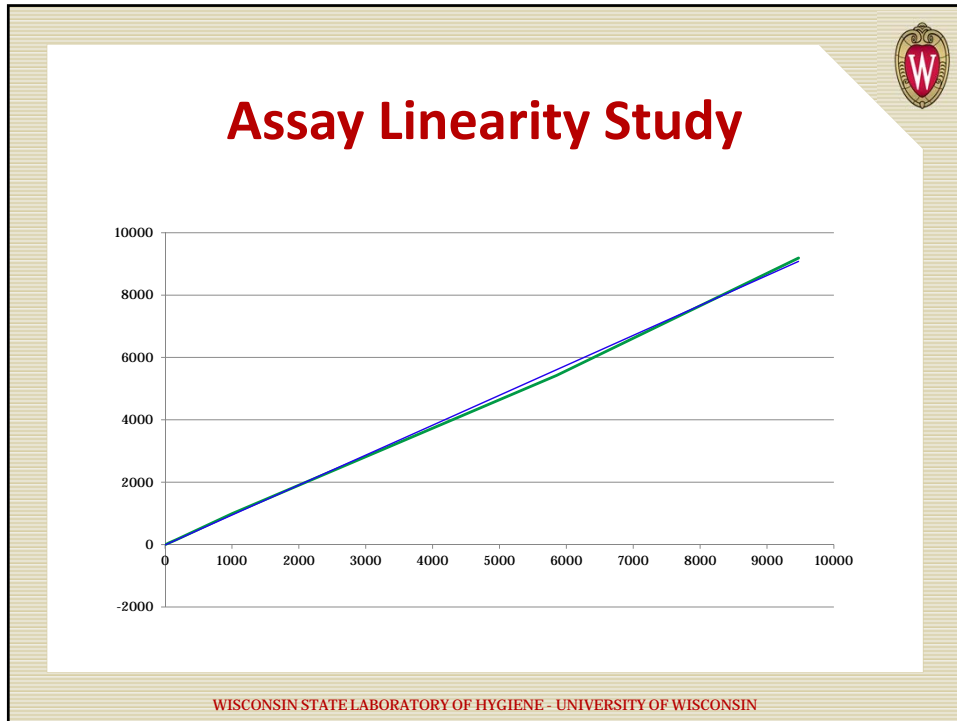


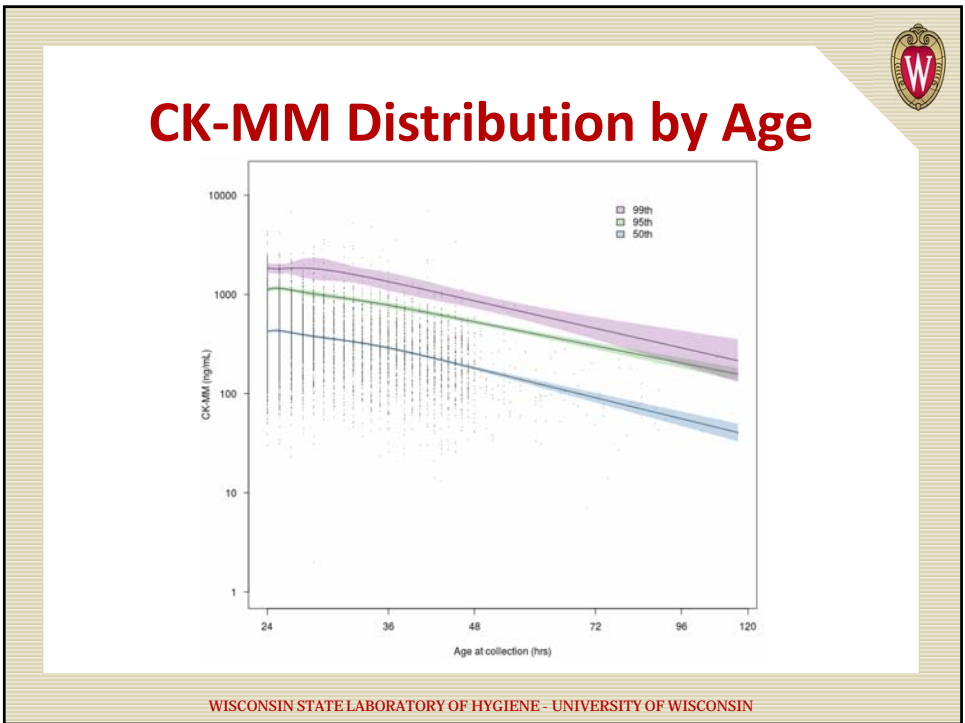
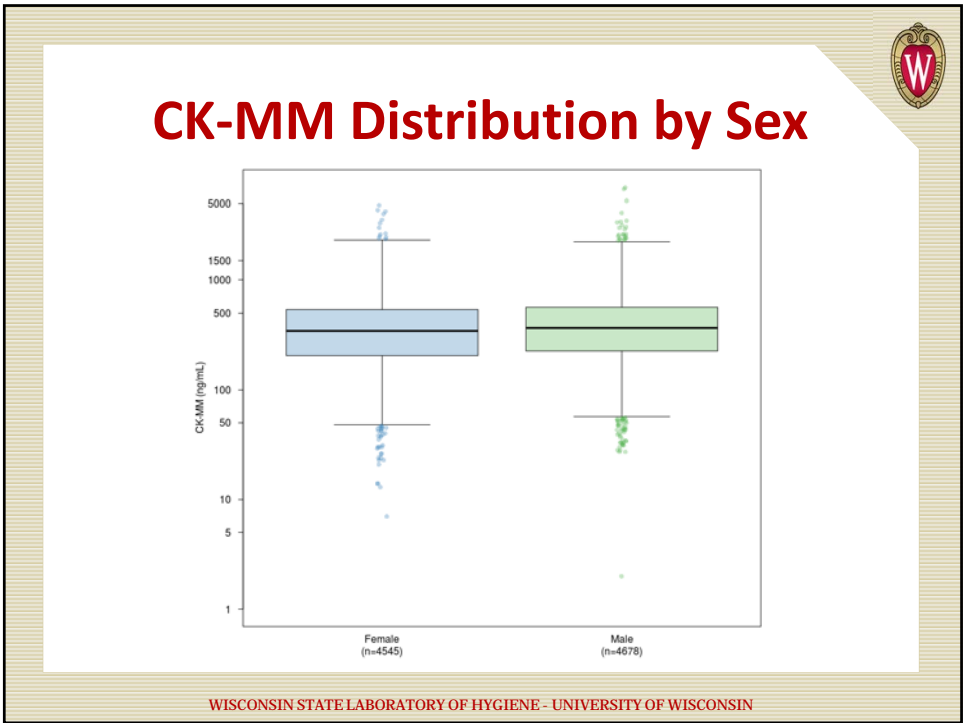
Assay Within-run Precision Control_Medium

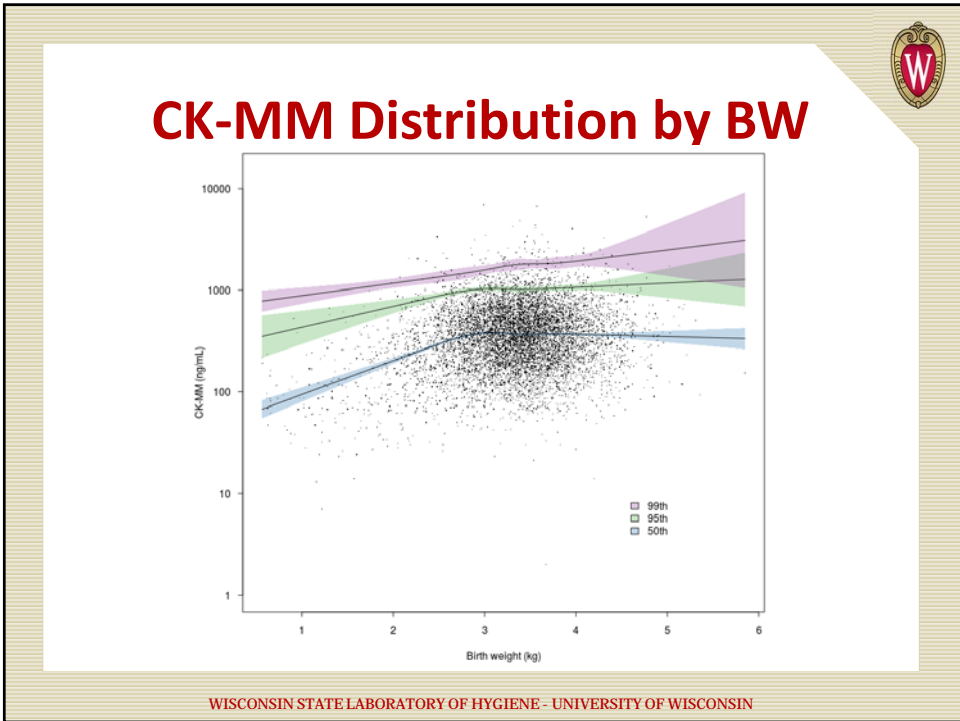
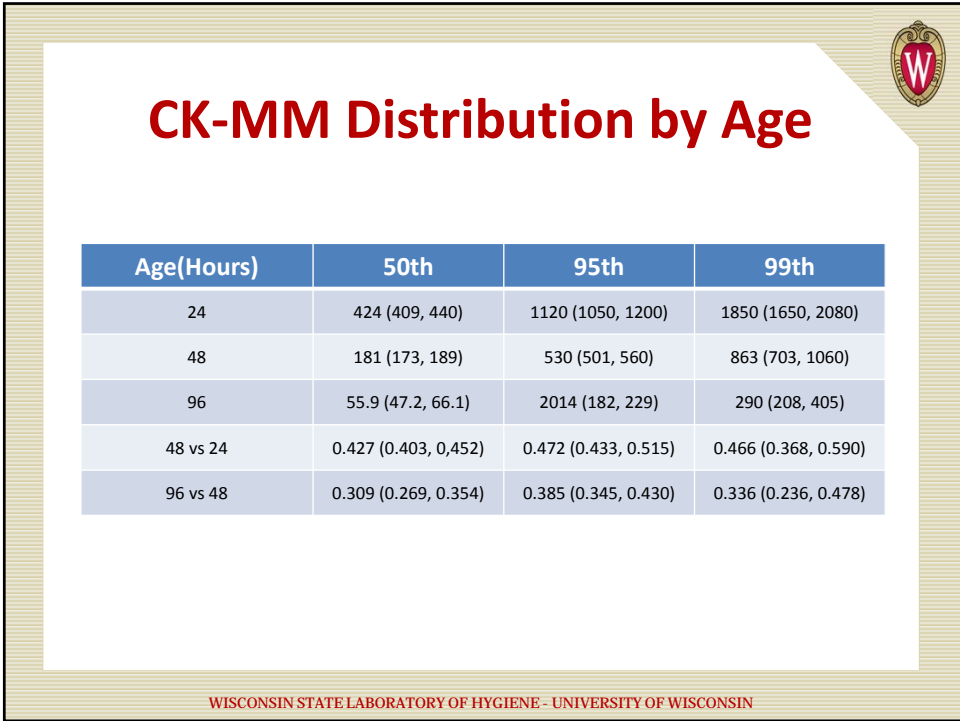
	R1	R2	R3	R4	R5	MEAN	SD	CV (%)
Day 1	522	522	449	463	522	495.6	36.49	7.4
Day 2	437	426	485	530	502	476	43.86	9.2
Day 3	453	463	435	501	463	463	24.12	5.2
Day 4	438	441	424	513	467	456.6	35.15	7.7
Day 5	476	421	422	469	519	461.4	41.15	8.9

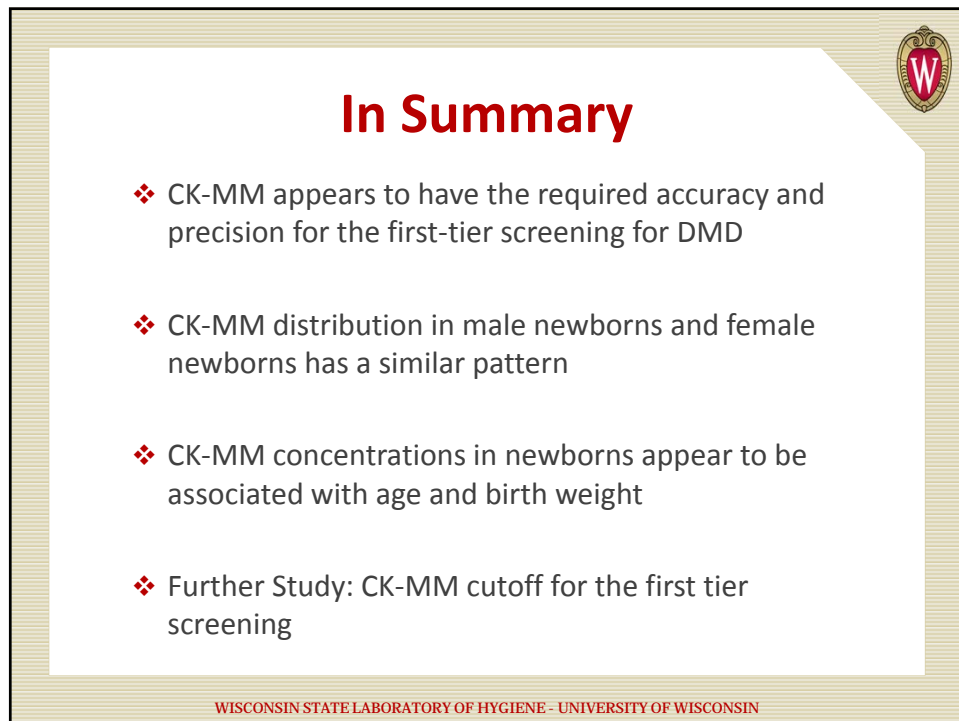
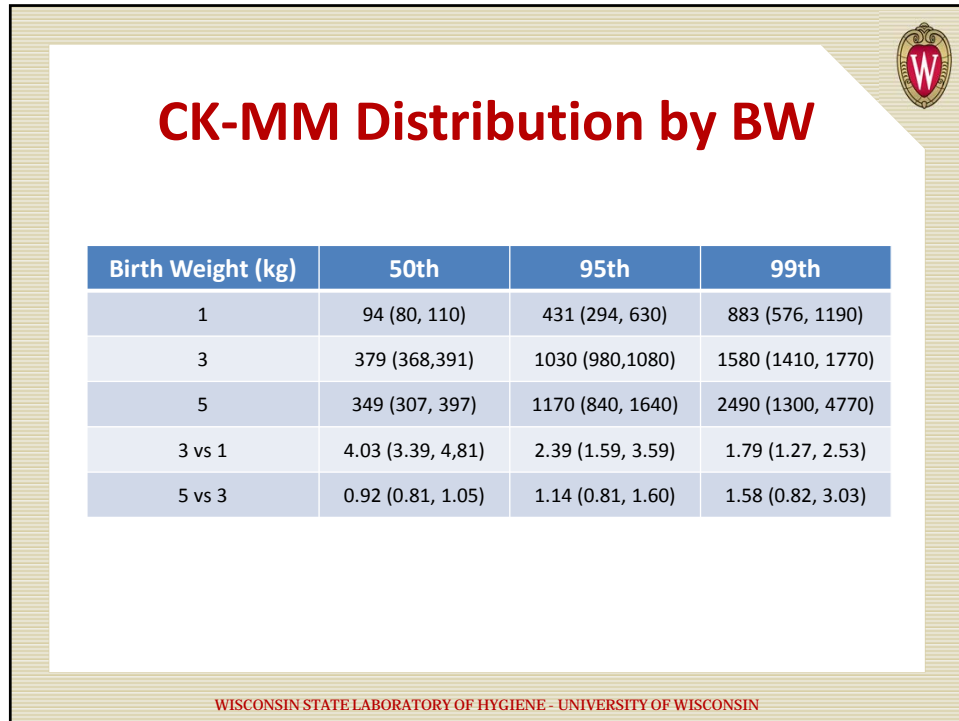
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