Wadsworth Center

New York State Department of Health

ERYTHROCYTE PROTOPORPHYRIN

Proficiency Test Report

Special Report for Aviv HF Participants

December 3, 2010

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Wadsworth Center The Governor Nelson A. Rockefeller Empire State Plaza P.O. Box 509 Albany, New York 12201-0509

Richard F. Daines, M.D.
Commissioner

James W. Clyne, Jr.
Executive Deputy Commissioner

December 3, 2010

Update – Toxicology Erythrocyte Protoporphyrin

Dear Laboratory Director:

I want to take this opportunity to provide an update on the status of our proficiency testing (PT) program for erythrocyte protoporphyrin (EP), and the issue of measurement traceability for the Aviv Biomedical, Inc. (Aviv) hematofluorometer (HF). This year, we suspended the regulatory grading process for EP, for both extraction and HF methods while we worked with Aviv to resolve the various issues. During this time, we continued to ship PT materials to participants and we collated results, but we postponed reporting aggregate data. The purpose of this letter is (a) to provide you with some feedback in the form of summary reports that show the current distribution of participant data and (b) to provide an update on our progress with Aviv.

We have attached summary PT reports from the first and second events, shipped March 24, 2010 and July 7, 2010, respectively. The calculated mean values should not be interpreted as either robust target values or as being traceable. We consider the 2010 PT events "Educational Quality Assurance" measures. They are provided for informational purposes only and serve to indicate how you are complying with your responsibilities for alternatives to PT under CLIA.

In August 2010, NYS program staff met with Aviv to review the process by which their **four master** HF instruments are calibrated, and how the calibration is maintained. We also reviewed how Aviv HF measurement traceability to the reference ethyl acetate extraction technique is maintained and verified. As a result of this meeting, NYS and Aviv agreed that two additional master HF instruments should be installed at our facility, along with an existing Aviv HF. Thus, there are now **seven** master instruments (Aviv) in the US: **four** at Aviv Biomedical in NJ; and **three** located at the NY State Wadsworth Center in Albany, NY. The latter instruments are co-located within the same reference laboratory that maintains the ethyl acetate extraction technique for EP. The first goal is to ensure that there is good agreement between each of the seven master instruments using stabilized blood-based materials produced by Aviv (RBC controls) and by NYS (PT samples). We are still evaluating data from these comparisons.

A second goal involves re-establishing traceability between EP measurements obtained on Aviv HFs (and reported as μg/dL FEP equivalent at hematocrit 35) and Free EP (FEP) measurements obtained by ethyl acetate extraction. Accomplishing this second goal will be much more challenging and may take some time. NYS now has the capability of analyzing human blood for EP on three master Aviv HFs, while simultaneously obtaining FEP data using the reference extraction technique. We now plan to work on re-establishing the link between Aviv HF and FEP by reference ethyl actetate extraction.

Therefore, we continue to request assistance from our participant laboratories. We need fresh, unhemolyzed human blood specimens that are elevated in EP **(i.e., only specimens that are ≥100 µg/dL).** Fresh blood (≤5 days old) can be shipped to us for analysis. If you are able to help with this task, we ask that you contact state laboratory staff at trel@wadsworth.org or at 518-473-0452. We would be able to report back the confirmed value for EP obtained by the ethyl acetate extraction technique.

As a PT program provider, we continue to maintain analytical capability for all three methods (reference acid extraction method, and Aviv and Helena HFs), and are in a unique position to assist manufacturers and users in re-establishing traceability.

Should you have any questions, feel free to contact us at trel@wadsworth.org or by telephone at 518-474-4924. Thank you once again for your patience as we attempt to resolve this difficult issue.

Sincerely,

Patrick J. Parsons, Ph.D.
Chief
Laboratory of Inorganic and Nuclear Chemistry

Mary F. Verostek, Ph.D.
Assistant Section Head
PT Program for Blood Lead/EP/Trace Elements

New York State Department of Health
Erythrocyte Protoporphyrin - Hematofluorometer Test Results, 2010 Event #1
SUMMARY

Lab Code	Method	Results (µg/dL whole blood)				
		HF10-01	HF10-02	HF10-03	HF10-04	HF10-05
104	Aviv Hematofluorometry	54	43	76	134	182
107	Aviv Hematofluorometry	54	45	80	131	174
110	Aviv Hematofluorometry	36	28	58	103	144
112	Aviv hematofluorometry	48	38	72	126	172
114	Aviv hematofluorometry	45	37	65	115	154
123	Aviv hematofluorometry	54	43	81	134	183
126	Aviv hematofluorometry	49	37	71	>80	>80
131	Aviv hematofluorometry	50	39	75	126	170
147	Aviv Hematofluorometry	48	38	71	123	169
155	Aviv hematofluorometry	52	37	71	120	158
156	Aviv hematofluorometry	55	41	74	128	175
158	Aviv hematofluorometry	52	39	77	>116	>116
160	Aviv hematofluorometry	47	35	69	117	>150
164	Aviv hematofluorometry	54	43	78	131	183
199	Aviv Hematofluorometry	51	40	77	128	172
221	Aviv hematofluorometry	48	38	73	124	168
272	Aviv hematofluorometry	51	43	74	124	173
293	Aviv Hematofluorometry	19	56	51	95	156
305	Aviv hematofluorometry	52	41	76	133	179
383	Aviv hematofluorometry	55	43	82	136	184
386	Aviv Hematofluorometry	51	40	77	124	169
398	Aviv Hematofluorometry	55	45	80	132	180
399	Aviv Hematofluorometry	47	37	70	123	167
406	Aviv Hematofluorometry	52	42	79	>120	>120
407	Aviv Hematofluorometry	45	37	69	115	157
447	Aviv Hematofluorometry	49	39	73	125	168
451	Aviv Hematofluorometry	47	43	69	113	156
454	Aviv Hematofluorometry	48	38	76	129	178
459	Aviv Hematofluorometry	50	42	72	120	163
Number of Sample Measurements:		29	29	29	26	25
	Mean values:	**49**	**40**	**73**	**123**	**169**
	Standard Deviation:	7.0	4.6	6.6	9.6	10.6
	RSD (%):	14.3	11.5	9.1	7.8	6.2

notes: Results reported as less than the detection limits are treated as zero for statistical and grading purposes.

New York State Department of Health
Erythrocyte Protoporphyrin - Hematofluorometer Test Results, 2010 Event #2
SUMMARY

Lab Code	Method	Results (µg/dL whole blood)				
		HF10-06	HF10-07	HF10-08	HF10-09	HF10-10
104	Aviv Hematofluorometry	82	124	90	160	50
107	Aviv Hematofluorometry	74	114	79	148	47
110	Aviv Hematofluorometry	56	91	59	115	29
112	Aviv Hematofluorometry	72	116	79	151	44
114	Aviv Hematofluorometry	67	107	78	142	43
123	Aviv Hematofluorometry	66	105	71	132	38
126	Aviv Hematofluorometry	75	123	81	149	44
131	Aviv Hematofluorometry	82	131	89	165	49
147	Aviv Hematofluorometry	73	115	79	158	44
155	Aviv Hematofluorometry	79	126	86	146	43
156	Aviv Hematofluorometry	73	120	79	140	47
158	Aviv Hematofluorometry	90	144	94	180	52
160	Aviv Hematofluorometry	72	111	71	140	37
164	Aviv Hematofluorometry	72	118	78	147	44
199	Aviv Hematofluorometry	83	132	94	170	53
221	Aviv Hematofluorometry	69	112	76	148	39
272	Aviv Hematofluorometry	87	131	88	160	47
293	Aviv Hematofluorometry	52	56	49	109	19
305	Aviv Hematofluorometry	76	113	80	147	43
383	Aviv Hematofluorometry	71	115	79	151	43
386	Aviv Hematofluorometry	74	121	80	151	43
398	Aviv Hematofluorometry	84	132	90	170	50
406	Aviv Hematofluorometry	84	123	81	154	45
407	Aviv Hematofluorometry	78	124	84	156	46
447	Aviv Hematofluorometry	72	117	76	144	42
451	Aviv Hematofluorometry	72	114	77	144	46
454	Aviv Hematofluorometry	79	130	88	163	48
459	Aviv Hematofluorometry	81	112	87	163	50
Number of Sample Measurements:		28	28	28	28	28
Mean values:		**75**	**117**	**80**	**150**	**44**
Standard Deviation:		8.4	15.9	9.7	15.1	6.9
RSD (%):		11.2	13.5	12.1	10.1	15.8

notes: Results reported as less than the detection limits are treated as zero for statistical and grading purposes.

New York State Department of Health
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METHOD NOTES

ATOMIC SPECTROMETRY METHODS

A-1 ETAAS-Z (Electrothermal atomic absorption spectrometry with Zeeman background correction)

A-2 ETAAS other (i.e., D_2, S-H background correction)

A-3 FAAS (Flame atomic absorption spectrometry)

A-4 CV-AAS (Cold vapor atomic absorption spectrometry)

A-5 HG-AAS (Hydride generation atomic absorption spectrometry)

A-6 AFS (Atomic fluorescence spectrometry)

A-7 Other

INDUCTIVELY COUPLED PLASMA

P-1 ICP-MS (Inductively coupled plasma - mass spectrometry)

P-2 DRC/CC-ICP-MS (ICP-MS used in the Dynamic Reaction Cell or Collision Cell mode)

P-3 ICP-AES/OES (ICP atomic/optical emission spectrometry)

P-4 HR-ICP-MS (High resolution ICP-MS)

P-5 ETV-ICP-MS (Electrothermal vaporization ICP-MS)

P-6 ID-ICP-MS (Isotope dilution ICP-MS)

P-7 Other

ELECTROCHEMICAL METHODS

E-1 ASV (Anodic stripping voltammetry without digestion)

E-2 ASV-LeadCare® (Anodic stripping voltammetry using the ESA LeadCare® system)

E-3 Fluoride specific electrode

E-4 Other

MOLECULAR FLUORIMETRY

F-1 EtOAc (Ethyl acetate-acetic acid extraction method for determination of erythrocyte protoporphyrin)

F-2 Aviv hematofluorometry (for determination of EP at hematocrit 35)

F-3 Helena ZPP (for determination of zinc protoporphyrin in μmol ZPP/mol heme)

F-4 Other

OTHER METHODS

If your method is not listed in the above list, please describe it briefly.