

Message

From: Surekha Gangakhedkar [/O=Theranos Organization/OU=FIRST ADMINISTRATIVE GROUP/CN=RECIPIENTS/CN=SUREKHAG]
Sent: 8/22/2013 5:53:48 PM
To: ELISA [elisa@theranos.com]; Nili Naik [innaik@theranos.com]; Samantha Zamora [szamora@theranos.com]; Darren Crandall [dcrandall@theranos.com]; Uyen Do [udo@theranos.com]; Andrew Kim [akim@theranos.com]
CC: Esther Chan [echan@theranos.com]
Subject: RE: Validation plans

Attached are the assay assignments that I forgot to add yesterday!

The file can also be found at –

T:\Assay_Systems\Assay Development Reports\LDT Validation plans>List of assays for 3.5.xls

From: Surekha Gangakhedkar
Sent: Wednesday, August 21, 2013 6:06 PM
To: ELISA; Nili Naik; Samantha Zamora; Darren Crandall; Uyen Do; Andrew Kim
Cc: Esther Chan
Subject: Validation plans

All,

In preparing for the upcoming validations, please see the attached list of assays that we will be starting with and the assignments. Validation will start in phases and will depend upon resources, most importantly readers, cartridges, clinical samples etc.

Esther has initiated the ordering of antibodies, analytes and controls.

The “assay owners” will be responsible for clinical sourcing and ordering. Other responsibilities include preparing assay specific documents. Attached is the validation plan to start reviewing and plugging in the assay specific details. A template will be circulated shortly for uniformity across the assays.

Also see the attached excel – tab named “TSH” to and modify it accordingly for your assays to estimate the number of cartridges needed. If you have been assigned assays for which you are not the developers – please check with me, Sharada, Tina and Ran and use the assay development reports and CLIA assay product inserts as guidelines.

Clinical correlation will require the following samples at a minimum. Depending upon the assay you may have to source out on the basis of gender, age, etc. If sufficient sample volume (100 uL) is available in inventory, we can use those samples.

Reference range study: 120 healthy patients

Accuracy/bias study: at least 40 samples, 20 normal, 20 outside reference range (can use Siemens RR)

Please save your templates/validation protocols at T:\Assay_Systems\Assay Development Reports\LDT Validation plans\ASSAYS.

Thanks,
Surekha

File Produced in Native Format

CPT	Owner(s)	3.0 20uL Protocol name	3.5 protocol						3.0 protocol			Tecan Diluent Transfer			Issues
			3.5 protocol		layout		3.0 protocol		Tecan	From Well	To Well (diluent and 3uL sample)	Diluent Volume (uL)			
			ELISA submitted	generated (svn)	ELISA submitted	generated (svn)	ELISA submitted	generated (svn)							
1	84443	thyroid stim hormone	Tina	Generic2_10x_coincubation 5-5 min svn-6235	Y	2810	Y	2812	Y	7474	Y	F3	D1	20	need to give MFG adjusted Dab conc (done)
2	82306	vitamin d_25 hydroxy	Tina		Y		Y		Y			F3	F8	12	
3	84153	psa, total	Karen	Generic2_10x_coincubation 5-5 min svn-6235	Y		Y					F3	D1	20	need to give MFG adjusted Dab conc (done)
4	84439	thyroxine, free	Sharada	Generic2_10x_coincubation	Y		Y					F3	D1	13	need to give MFG adjusted Dab conc (done)
5	84702	chorionic gonadotropin	Ling/Uyen/emma	Generic2_25x_CoIncubation_5_5	Y		Y		Y	7472		F3	F8	27	
6	82607	vitamin b-12	Sharada/Darren												
7	87340	hepatitis b surface ag, ela	Andy	HBSAg_5x_10Pre_CoIncubation											
8	86592	syphilis non-trep qual	Andy	Generic2_25x											
9	86703	hiv-1/hiv-2, single	Michelle/Nili	Generic2_100X_PSW_10-10-10											
10	86618	lyme disease antibody (IgG and IgM)	Nili	Generic2_50x_PSW_5_5_5_svn_6341	Y		Y		Y	7462		F3	F8	27	
11	84484	troponin, quant (cNI)	Ran/Tiffany	Generic2_5X_CoIncubation_svn_6171											5x possible with 3uL sample?
12	84436	thyroxine, total	Tina	TT4_2-1_svn_6157											
13	86803	hepatitis c ab	Andy	Generic2_25X_PSW_svn_5735											
14	82746	folic acid serum, blood ?	Ran/Karen/Darren	Folate_treatment_1_24x_1											
15	86038	antinuclear antibodies (IgG)	Sharada/Andy	Generic_2_25x_PSW_2_2_1_svn_6335											
16	83001	gonadotropin (fsh)	Ling/Uyen	Angiogenesis2_D											
17	84403	total testosterone	Tina/Uyen	TST_Total_Free											
18	86762	rubella antibody, IgM	Salina	Generic2_100x_PSW_svn_5766	Y		Y		Y	7468		F3	F8	27	
19	86317	rubella antibody IgG	Salina	RVlgG_VZVlgG_svn_5730	Y		Y		Y	7470		F3	F8	27	
20	82670	estradiol	Tina/Emma	Estradiol_5x_5_10Pre_svn_6439											5x possible with 3uL sample?
21	84479	thyroid (t3 or t4)	Tina/Emma	Generic2_25x_coincubation_2-1											
22	82553	creatine, mb fraction	Emma/Samantha	Generic2_25x_coincubation 2-1 min											
23	84146	prolactin	Emma/Samantha	Generic2_10x_10-10-10											will need to give MFG adjusted Dab conc
24	84480	triiodothyronine (t3)	Emma/Uyen	TT3_25X_5-5_svn_6415											
25	83002	gonadotropin (lh)	Tiffany	Fertility_1_FSH_LH_Mux_Mix35											
26	86235-01	nuclear antigen antibody, SSB	Tiffany/Salina	Generic2_25x_PSW_svn_5735											
27	86235-02	nuclear antigen antibody, SSA	Tiffany/Salina	Generic_2_50x_PSW_5_5_5_svn_6341											
28	86235-03	nuclear antigen antibody, Sm	Tiffany/Salina	Generic2_5x_PSW_5721											5x possible with 3uL sample?
29	86235-04	nuclear antigen antibody, RNP	Tiffany/Salina	Generic2_25x_PSW_svn_5735											
30	86235-05	nuclear antigen antibody, Scl-70	Tiffany/Salina	Generic2_10x_svn_5722											
31	86235-06	nuclear antigen antibody, Jo-1	Tiffany/Salina	Generic2_50x_PSW_svn_5749											
32	86706	hep b surface antibody	Andy	Generic_2_5X_Co-Incubation_5_5min											5x possible with 3uL sample?
33	83970	parathormone	Tina/Andrew	Generic2_10x_CoIncubation											will need to give MFG adjusted Dab conc
34	86308	heterophile antibodies (IgM)	Salina	Generic2_100x_PSW_svn_5766											5x possible with 3uL sample?
35	82105	alpha-fetoprotein, serum	Karen	Generic2_5x_PSW_5721											
36	87400-1	influenza a/b, ag, eia	Karen	Flu_A_B Svn 7003											
37	87400-2	influenza a/b, ag, eia	Karen	Flu_A_B Svn 7003											
38	86431	rheumatoid factor, quant (IgM)													Repeats on Siemens Advia
39	84144	progesterone	Uyen	Estradiol_Progesterone_Mux_10_svn_3833											
40	86787	varicella-zoster antibody	Darren	RVlgG_VZVlgG_svn_5730	Y		Y		Y	7466		F3	F8	27	
41	84402	testosterone (free)	Tina/Uyen	TST_Total_Free											
42	86665	epstein-barr antibody IgG	Tiffany/Salina	Generic2_25x_PSW_svn_5735											
43	86704	hep b core antibody, total	Andy	Generic_2_25X_PSW_5-5-5_min											
44	86376	microsomal antibody	Andrew	Generic2_1000x_PSW_5-5-5											
44	84481	ft-3, free	Emma/Uyen	Generic2_5x_CoIncubation_5-5											5x possible with 3uL sample?
45	86709	hep a antibody, igm		Generic2_10x_PSW_svn_5724											Antibody discontinued, back in development
46	86800	thyroglobulin antibody, IgG	Tina	AntiTgAb_svn_6701	Y		Y		Y	7464		F3	F8	27	
47	86705	hep b core antibody, igm	Salina/Nili	Generic_2_25X_PSW_5-5-5_min											
48	82785	ige	Karen	Generic2_50X											
49	86430-1	rheumatoid factor test, IgG	Ling	Generic2_25x_PSW_svn_5735											
49	86430-2	rheumatoid factor test, IgA	Ling	Generic2_25x_PSW_svn_5735											
50	86747-01	parvovirus antibody, IgG	Ling	Generic2_100x_PSW_10_10_10											
51	82784-4	igd	Tiffany	Generic2_15000X_PSW											
52	86696	herpes simplex type 2	Michelle/Nili	Generic2_25x_PSW_5-5-5											Antigen not available for commercial use, back in development
52	86695	herpes simplex	Michelle/Nili	Generic2_10x_PSW_5-5-5											will need to give MFG adjusted Dab conc
53	82677	estriol	Emma/Andrew	Generic2_10x_CoIncubation											will need to give MFG adjusted Dab conc
54	83880	natrluretic peptide	Emma/Andrew	Generic2_5x_CoIncubation											5x possible with 3uL sample?
55	82627	dehydroepiandrosterone sulfate (dheas)	Ran/Tiffany	Generic2_competitive_50x_10_10											
56	86765-01	rubeola antibody, IgG	Salina/Darren	Measles_mumps_ab_50x_100x_10x10x10_svn_6607											
57	86765-02	rubeola antibody, IgM	Salina/Darren	Generic2_100x_PSW_svn_5766											
58	86735	mumps antibody, IgG	Salina/Darren	Measles_MumpsAb_50x_100x_10-10-10_svn_6607											
59	G0431QW	Cotinine, Serum and Urine	Sharada	Generic2_25x_coincubation_10x10											
60	81025	pregnancy, urine	Ling/Uyen/Emma	Generic2_25x_CoIncubation_5_5											

		Owner(s)	3.0 Protocol name
84443	thyroid stim hormone	Tina	
82306	vitamin d, 25 hydroxy	Tina	
84153	psa, total	Karen	
84439	thyroxine, free	Sharada	
84702	chorionic gonadotropin	Emma/Uyen	
82607	vitamin b-12		
87340	hepatitis b surface ag, eia	Andy	
86592	syphilis non-trep qual	Andy	
86703	hiv-1/hiv-2, single	Michelle/Samantha	
86618	lyme disease antibody (IgG and IgM)		
84484	troponin, quant (tcNI)	Ran	
84436	thyroxine, total	Tina	
86803	hepatitis c ab	Andy	
82746	folic acid serum, blood ?	Ran	
86038	antinuclear antibodies (IgG)	Sharada/Andy	
83001	gonadotropin (fsh)	Tina/Uyen	
84403	total testosterone	Tina/Uyen	
86762	rubella antibody, IgM	Salina	
86317	rubella antibody IgG	Salina	
82670	estradiol	Tina/Emma	
84479	thyroid (t3 or t4)	Tina/Emma	
82553	creatine, mb fraction	Emma/Samantha	
84146	prolactin	Emma/Samantha	
84480	triiodothyronine (t3)	Emma/Uyen	
83002	gonadotropin (lh)	Tiffany	
86235-01	nuclear antigen antibody, SSB	Tiffany/Salina	
86235-02	nuclear antigen antibody, SSA	Tiffany/Salina	
86235-03	nuclear antigen antibody, Sm	Tiffany/Salina	
86235-04	nuclear antigen antibody, RNP	Tiffany/Salina	
86235-05	nuclear antigen antibody, Scl-70	Tiffany/Salina	
86235-06	nuclear antigen antibody, Jo-1	Tiffany/Salina	

86706	hep b surface antibody	Andy	
83970	parathormone		
86308	heterophile antibodies (IgM)		
82105	alpha-fetoprotein, serum		
87400-1	influenza a/b, ag, eia		
87400-2	influenza a/b, ag, eia		
86431	rheumatoid factor, quant (IgM)		
84144	progesterone		
86787	varicella-zoster antibody		
84402	testosterone		
86665	epstein-barr antibody IgG		
86704	hep b core antibody, total		
86376	microsomal antibody		
84481	ft-3, free		
86709	hep a antibody, igm		
86800	thyroglobulin antibody, IgG		
86705	hep b core antibody, igm		
82785	ige		
86430-1	rheumatoid factor test, IgG		
86430-2	rheumatoid factor test, IgA		
86747-01	parvovirus antibody, IgG		
82784-4	igd		
86696	herpes simplex type 2		
86695	herpes simplex		
82677	estriol		
83880	natriuretic peptide		
82627	dehydroepiandrosterone sulfate (dheas)		
86765-01	rubeola antibody, IgG		
86765-02	rubeola antibody, IgM		
86735	mumps antibody, IgG		
G0431QW	Cotinine, Serum and Urine		
81025	pregnancy , urine	Emma	