

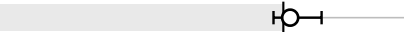
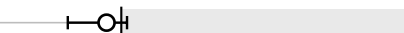
Untitled study

hCG (mIU/mL) · Near-cutoff precision ❷ Undecided

1 of 3 questions judged · C50 concentration met · C95 concentration and C5 concentration undecided

Study date Not recorded

Table 1. Acceptance criteria

Question	Limit	Allowed	Finding	Result
C50 concentration	Between 9.5 mIU/mL and 10.5 mIU/mL		9.88 mIU/mL 9.43–10.33	✓ Met
C95 concentration	≤ 12 mIU/mL		12.29 mIU/mL 11.58–13.62	❷ Undecided ^a
C5 concentration	≥ 8 mIU/mL		7.48 mIU/mL 6.11–8.20	❷ Undecided ^b

^a C95 = 12.29 mIU/mL is outside the tested concentrations (8 to 12 mIU/mL). At face value it does not meet the criterion.

^b C5 = 7.48 mIU/mL is outside the tested concentrations (8 to 12 mIU/mL). At face value it does not meet the criterion.

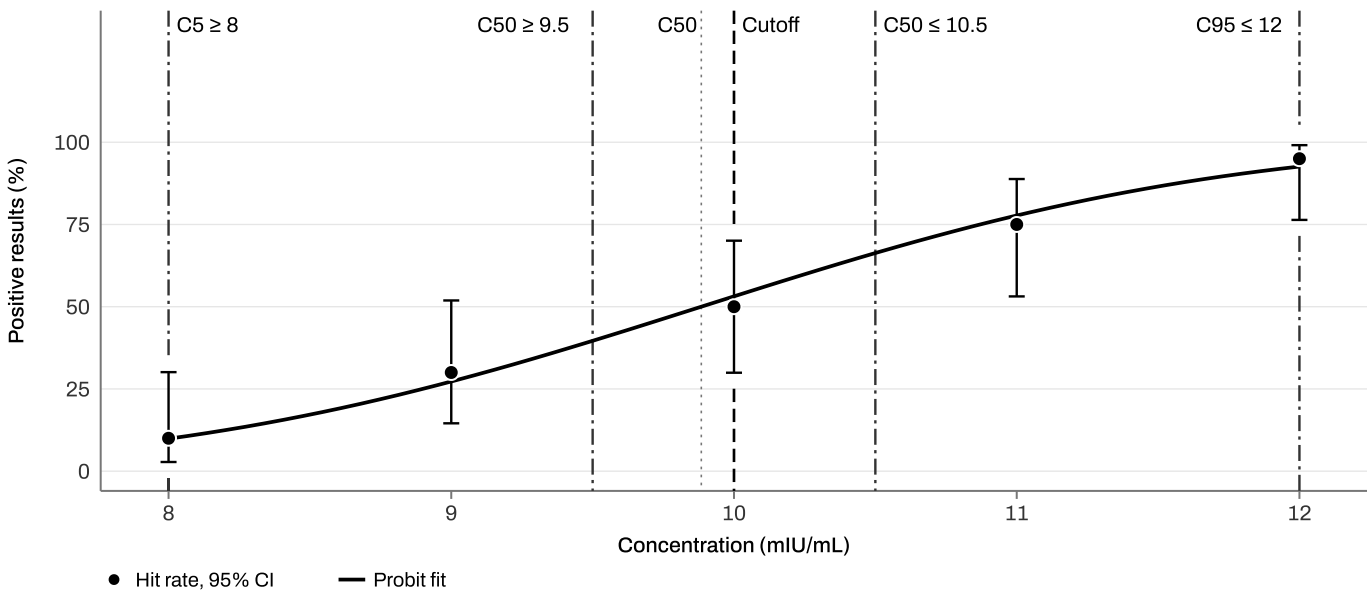


Figure 1. Positive results by concentration with 95% CIs and the fitted probit curve.

The assay cutoff lies within the C5–C95 interval.

Study details

Data	100 included	Cutoff	10 mIU/mL	Concentrations	5
Positive category	positive				

Signed off by

Date

A Data listing

Source: manual entry. 100 rows, all included.

Study row	Sample	Conc. (mIU/mL)	Result	Replicate
1	C8	8	positive	1
2	C8	8	positive	2
3	C8	8	negative	3
4	C8	8	negative	4
5	C8	8	negative	5
6	C8	8	negative	6
7	C8	8	negative	7
8	C8	8	negative	8
9	C8	8	negative	9
10	C8	8	negative	10
11	C8	8	negative	11
12	C8	8	negative	12
13	C8	8	negative	13
14	C8	8	negative	14
15	C8	8	negative	15
16	C8	8	negative	16
17	C8	8	negative	17
18	C8	8	negative	18
19	C8	8	negative	19
20	C8	8	negative	20
21	C9	9	positive	1
22	C9	9	positive	2
23	C9	9	positive	3
24	C9	9	positive	4
25	C9	9	positive	5
26	C9	9	positive	6
27	C9	9	negative	7
28	C9	9	negative	8
29	C9	9	negative	9
30	C9	9	negative	10
31	C9	9	negative	11
32	C9	9	negative	12
33	C9	9	negative	13
34	C9	9	negative	14
35	C9	9	negative	15
36	C9	9	negative	16
37	C9	9	negative	17
38	C9	9	negative	18
39	C9	9	negative	19
40	C9	9	negative	20
41	C10	10	positive	1
42	C10	10	positive	2
43	C10	10	positive	3

Study row	Sample	Conc. (mIU/mL)	Result	Replicate
44	C10	10	positive	4
45	C10	10	positive	5
46	C10	10	positive	6
47	C10	10	positive	7
48	C10	10	positive	8
49	C10	10	positive	9
50	C10	10	positive	10
51	C10	10	negative	11
52	C10	10	negative	12
53	C10	10	negative	13
54	C10	10	negative	14
55	C10	10	negative	15
56	C10	10	negative	16
57	C10	10	negative	17
58	C10	10	negative	18
59	C10	10	negative	19
60	C10	10	negative	20
61	C11	11	positive	1
62	C11	11	positive	2
63	C11	11	positive	3
64	C11	11	positive	4
65	C11	11	positive	5
66	C11	11	positive	6
67	C11	11	positive	7
68	C11	11	positive	8
69	C11	11	positive	9
70	C11	11	positive	10
71	C11	11	positive	11
72	C11	11	positive	12
73	C11	11	positive	13
74	C11	11	positive	14
75	C11	11	positive	15
76	C11	11	negative	16
77	C11	11	negative	17
78	C11	11	negative	18
79	C11	11	negative	19
80	C11	11	negative	20
81	C12	12	positive	1
82	C12	12	positive	2
83	C12	12	positive	3
84	C12	12	positive	4
85	C12	12	positive	5
86	C12	12	positive	6
87	C12	12	positive	7
88	C12	12	positive	8
89	C12	12	positive	9

Study row	Sample	Conc. (mIU/mL)	Result	Replicate
90	C12	12	positive	10
91	C12	12	positive	11
92	C12	12	positive	12
93	C12	12	positive	13
94	C12	12	positive	14
95	C12	12	positive	15
96	C12	12	positive	16
97	C12	12	positive	17
98	C12	12	positive	18
99	C12	12	positive	19
100	C12	12	negative	20

1 Results

1.1 Results by concentration

Table 2. Results by tested concentration

Concentration (mIU/mL)	Samples	Results	Nonreportable	Positive	Hit rate (%)	95% Wilson CI (%)
8	1	20	0	2/20	10.00	2.79–30.10
9	1	20	0	6/20	30.00	14.55–51.90
10	1	20	0	10/20	50.00	29.93–70.07
11	1	20	0	15/20	75.00	53.13–88.81
12	1	20	0	19/20	95.00	76.39–99.11