立 人 醫 事 檢 驗 所
Lezen Reference Lab

公告編碼 ：20210903-01
受 文 者 ：貴 單位主管鈞鑒
日　　期 ：2021 年 09 月 03 日
公告事項 ：檢驗項目 Cyfra 21-1，自 2021 年 10 月 01 日起更改參考值。
說　　明 ：自 2021 年 10 月 01 日起檢驗項目 Cyfra 21-1 因應原廠試劑說明書變更參考值(如附件標記區)，修改如下:

	變更前	變更後
參考值	< 3.3 ng/mL	≦ 2.37 ng/mL
來源說明	採用單一良性肺部疾病(Benign lung disease)族群之 95%信賴區間結果。	採用三個族群的統計結果；三個族群分別為： 1.健康的男性與女性(含吸菸者與未吸菸者) 2.良性疾病(Benign disease，含肺部疾病) 3.癌症(含肺及其他部位)

*受影響之檢體自10月01日(含)起操作之檢體
*QP-1802 採檢手冊2021年第153頁 (http://www.lez.com.tw/)

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特此告知　造成不便　敬請見諒！

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Elecsys CYFRA 21-1

cobas®

There is no high-dose hook effect at CYFRA 21-1 concentrations up to 2000 ng/mL.

Pharmaceutical substances
In vitro tests were performed on 16 commonly used pharmaceuticals. No interference with the assay was found.

In addition, the following special cancer drugs were tested. No interference with the assay was found.

Special cancer drugs

Drug	Concentration tested mg/L
Doxorubicin	120
Cyclophosphamide	1000
Cisplatin	225
5-FU	500
Methotrexate	1000
Tamoxifen	50
Mitomycin	25
Carboplatin	1000
Etoposide	400
Paclitaxel	265
Clotrimazole	0.3
Dexamethasone	20
Leucovorin	750
Melphalan	15
Tarceva	150

In rare cases, interference due to extremely high titers of antibodies to analyte-specific antibodies, streptavidin or ruthenium can occur. These effects are minimized by suitable test design.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

Limits and ranges

Measuring range

0.1-500 ng/mL (defined by the Limit of Blank and the maximum of the master curve). Values below the Limit of Blank are reported as < 0.1 ng/mL. Values above the measuring range are reported as > 500 ng/mL (or up to 1000 ng/mL for 2-fold diluted samples).

Lower limits of measurement

Limit of Blank, Limit of Detection and Limit of Quantitation

Limit of Blank = 0.1 ng/mL

Limit of Detection = 0.3 ng/mL

Limit of Quantitation = 0.5 ng/mL

The Limit of Blank, Limit of Detection and Limit of Quantitation were determined in accordance with the CLSI (Clinical and Laboratory Standards Institute) EP17-A2 requirements.

The Limit of Blank is the 95th percentile value from n ≥ 60 measurements of analyte-free samples over several independent series. The Limit of Blank corresponds to the concentration below which analyte-free samples are found with a probability of 95 %.

The Limit of Detection is determined based on the Limit of Blank and the standard deviation of low concentration samples. The Limit of Detection corresponds to the lowest analyte concentration which can be detected (value above the Limit of Blank with a probability of 95 %).

The Limit of Quantitation is the lowest analyte concentration that can be reproducibly measured with an intermediate precision CV of ≤ 20 %.

An internal study was performed based on guidance from the CLSI, protocol EP17-A2. Limit of Blank and Limit of Detection were determined to be the following:

Limit of Blank = 0.069 ng/mL

Limit of Detection = 0.125 ng/mL

For Limit of Quantitation ≥ 4 human serum samples were measured over 5 days with 5 replicates on 1 analyzer. With an intermediate precision CV of ≤ 20 % the Limit of Quantitation was 0.324 ng/mL.

Dilution

Samples with CYFRA 21-1 concentrations above the measuring range can be diluted with Diluent Universal. The recommended dilution is 1:2 (either automatically by the analyzer or manually). The concentration of the diluted sample must be > 225 ng/mL.

After manual dilution, multiply the result by the dilution factor.

After dilution by the analyzers, the software automatically takes the dilution into account when calculating the sample concentration.

Expected values

Normal CYFRA 21-1 values are expected to be ≤ 2.37 ng/mL.

The following table shows the results of three separate cohorts. The first study represents the distribution of expected results from 240 apparently healthy men and women equally divided into smokers and nonsmokers. The second study represents the distribution of expected results from 195 benign disease conditions other than cancers, and the third study represents the distribution of expected results from different cancers, including lung cancer.

Elecsys CYFRA 21-1 distribution of values by cohort						
	No. of subjects	**0.3-2.37 ng/mL**	**2.38-5.0 ng/mL**	**5.01-20.0 ng/mL**	**20.01-100 ng/mL**	**> 100 ng/mL**
Apparently healthy	**240**					
All normals	240	228	12	0	0	0
Nonsmokers	120	111	9	0	0	0
Smokers	120	117	3	0	0	0
Normal females	125	119	6	0	0	0
Nonsmokers	63	59	4	0	0	0
Smokers	62	60	2	0	0	0
Normal males	115	109	6	0	0	0
Nonsmokers	57	52	5	0	0	0
Smokers	58	57	1	0	0	0
Benign conditions	**195**					
Benign lung disease	75	70	5	0	0	0
CHF[b)]	40	29	11	0	0	0
Benign kidney disease	40	8	24	8	0	0
Benign liver disease	40	35	4	1	0	0
Cancer	**440**					
Lung cancer	120	53	33	27	5	2
Bladder cancer	40	13	9	12	5	1
Breast cancer	40	32	5	3	0	0
Cervical cancer	40	28	11	1	0	0
ESCC[c)]	40	21	12	6	1	0
GI tract cancer	40	23	10	6	1	0

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