

National Biochemical Reference Ranges for Adult's Age Group

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ABSTRACT:

BACKGROUND:

Reference range basically originates in what is most prevalent in a reference group taken from the healthy population. It is a basis for a physician or other health professional to interpret a set of results for a particular patient. In our country it's preferable to redistribute a normal list of values instead of the old one, taking into consideration a specific reference ranges for population with any factor that may affects their measurement as, climate, type of food, and race. It should comprise both sexes; all age groups and between which 95% of values of a reference group fall into after enrollment of the inclusion/exclusion criteria.

OBJECTIVE:

To establish a reference ranges of some biochemical parameters for healthy adults' population.

METHODS:

one thousand healthy individual (aged 20-50 year), with 500 male and 500 female, selected from Baghdad city, from AL-Mammon University College and Ministry of Health, were recruited for the study between march. 2011-april. 2012 after they were subjected to an inclusion/exclusion criteria, reference ranges of some biochemical parameters was constructed by using the parametric methods to estimate 2.5 and 97.5 percentiles of distribution.

RESULTS:

Specific ranges for some biochemical parameters shows somewhat a little bit difference in comparison to their counterparts from other countries. Moreover it was clearly noticed that the present dependent-format missed many important parameters as (HDL-Cholesterol), (LDL-Cholesterol) in addition to missing sex and age difference. Results also shows statistically significant higher values in female than male for (HDL-Cholesterol) ($p=0.000$), (Total Protein) ($p=0.000$), and lower values in females than male for (Uric Acid) ($p=0.000$), (CREAT) ($p=0.000$), (Blood Urea) ($p=0.000$).

CONCLUSION:

There is a need for the national clinical chemistry laboratory to establish its own ranges for both sexes to all age groups, and to redistributes them in a new format.

KEYWORDS: parametric methods.

INTRODUCTION:

A reference range of a parameter is a set of values used in the interpretation of a clinical report to establish whether a patient has a certain pathological disorder, and a group-base reference range is used in the interpretation of laboratory report⁽¹⁾. Published reference ranges in literature do not sometimes represent adequately the specific population from which the patient comes from, based on age, sex, genetics, diet, and altitude. In addition, reference ranges produced by reagent manufacturers are determined from analysis of blood samples of a few health workers who do not represent the general population. It is therefore recommended that each

national clinical chemistry laboratory should establish its own reference range for biochemical parameters⁽¹⁾.

The standard definition of a reference range for a particular measurement is defined as the prediction interval between which 95% of values of a reference group fall into, in such a way that 2.5% of the time a sample value will be less than the lower limit of this interval, and 2.5% of the time it will be larger than the upper limit of this interval, whatever the distribution of these values. Reference ranges that are given by this definition are sometimes referred as standard ranges. A standard reference range generally denotes the one in healthy individuals, or without any known condition that directly affects the ranges being established. These are likewise established using reference groups from the

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healthy population, and are sometimes termed normal ranges or normal values (and sometimes "usual" ranges/values). However, using the term normal may not be appropriate as not everyone outside the interval is abnormal, and people who have a particular condition may still fall within this interval (physiological). Preferably, there should be specific reference ranges for each subgroup of the population that has any factor that affects the measurement, such as, for example, specific ranges for each sex, age group,

race or any other general determinant⁽⁷⁾. Methods for establishing reference ranges are mainly based on assuming a normal distribution or a log-normal distribution, or directly from percentages of interest⁽⁴⁾. Normal distribution; when assuming a normal distribution, the reference range is obtained by measuring the values in a reference group and taking two standard deviations either side of the mean. The 95% prediction interval is often estimated by assuming a normal distribution of the measured parameter, to account for these estimations, the 95% prediction interval (95% PI) is calculated as:

$$95\%PI = mean \pm t_{0.975,n-1} \sqrt{\frac{n+1}{n}} sd,$$

Where $t_{0.975,n-1}$ is the 97.5% quintile of a

with n-1 freedom? When Student's t-distribution the sample size is large ($n \geq 30$)

$$t_{0.975,n-1} \simeq 2.$$

In case of a bimodal distribution, two reference ranges can be established for the two different groups of people, making it possible to assume a normal distribution for each group. This bimodal pattern is commonly seen in tests that differ between men and women⁽⁸⁾.

MATERIALS AND METHODS:

One thousand healthy individual (aged 20-60 yr), with 500 male and 500 female, selected from Baghdad city were enrolled in this study between (march, 2011-april, 2012), all participants were subjected for inclusion/exclusion criteria: Iraqi citizen, not obese ($BMI < 24 \frac{KG}{M^2}$), not hypertensive (only those subjects with a BP $< 120/80$ mm Hg were included in the study), not pregnant, not involved in any excessive exercise, not febrile, not under any medication, fasting, not taking any oral contraceptives, none alcohol nor tobacco users, no genetic disorder, doesn't complain from chronic diseases. A questionnaire was administered to consenting study subjects. Collected sera were analyzed for glucose, blood urea, creatinine, uric acid, inorganic phosphate, protein, albumin, alanine amino transferase, aspartate amino transferase, alkaline phosphatase, total serum bilirubin, calcium, cholesterol, triglyceride, using mindray System version BS-200. To ensure accuracy and

precision, calibration procedure was carried out using multicalibrator sera. Quality control checks were kept daily using multisera normal (Randox Laboratories Ltd) and all values for all the analyses were within $\pm 2SD$ of their target mean.

RESULTS:

The accuracy of the assay methods used in the determination of all the parameters in the quality control sample was in close agreement with the assigned value. Table 1 explored the (mean \pm SD), ranges, and reference interval for adults participants for both sexes, in addition to their number.

In Appendix (1,2), it was clearly noticed that the present format missed many important parameters as (HDL-C), (LDL-C), moreover, sex and age difference wasn't noticed in this format which is very important for a physician or other health professional to interpret a set of results for a particular disorders. Table two shows the values of the main studied parameters in relation to their counterpart in appendix 1 and 2 in which glucose, albumin, alanine amino transferase, aspartate amino transferase and alkaline phosphatase show higher values, but cholesterol, triglyceride, blood urea, creatinine, and uric acid show less values in this study than those in appendix (1,2). While table three show the studied specific ranges in comparison to their counterparts from other countries, were (ALT, AST) lower in both sexes than other, (ALP) higher than American and Kuwait in both sexes

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but lower than Kenyan values, the upper ranges of glucose is lower than those for American but nearly equal to Kenyan and Kuwait ranges, for protein the male upper range were lower than the upper ranges in other countries, while albumin interval is higher in both sexes. Also Iraqi female lower ranges for (UA) are lower than others, urea upper range is higher than other' on the contrary' in female the upper range is lower, creatinine upper ranges is lower in both sexes

than Kenyan ,lastly the upper ranges of phosphorous is lower than Kenyan values in male and female. Table 1 shows the established sex specific reference ranges for some biochemical parameters in adult. Results show statistically significant higher values in female than male for (HDL-C) (p=0.000), (TP) (p=0.000), and lower values in females than male for (UA) (p=0.000), (CREAT) (p=0.000), (BUN) (p=0.000)

Table 1: Specific reference ranges for adults (20-40) years.

Analyte (unit)	Gender	Number	Mean ± SD	Range	Reference interval
GLU(mg/dl)	M	400	87,3±14,8	72-101	56,8-110,8
	F	500	80,7±14,8	70-100	56-113,3
Chol(mg/dl)	M	=	148±20	113-203	88-198
	F	=	127±30	94-190	96-190,0
TG(mg/dl)	M	=	97,8±39,8	28-180	17,2-176,4
	F	=	94±37,9	27-188	20,3-178
HDL(mg/dl)	M	=	33,4±7,9	22-44	9,7-47,2
	F	=	37,4±8,2	30-50	20-49
ALT(iu/L)	M	=	12,20±7,9	7-20	0-27
	F	=	11,34±3,1	7-20	0,1-17,06
AST(iu/L)	M	=	13,9±0,9	9-20	2,1-20
	F	=	13,7±3,4	8-20	7,76-20,4
ALP(iu/L)	M	=	74,2±23,8	50-172	17,0-112
	F	=	57,4±19,9	40-100	17,0-99,3
Blood urea(mmol/L)	M	=	0,3±1,3	2-7	3,07-8
	F	=	3,7±1	2-7	2,08-0,76
CREAT (mmol/L)	M	=	77,0±21	70-103	30,433-119,70
	F	=	70,8±9,3	50-90	47,2-84,4
U.A (mmol/L)	M	=	4,4±0,9	3-7	2,7-7,2
	F	=	3,0±1	2-5	1,0-0,0
Ca (mg/dl)	M	=	9,4±0,0	8,0-10,0	8,42-10,38
	F	=	9,1±0,0	8,3-10,4	8,2-10,2
PHOS (mmol/l)	M	=	3,2±0,8	2,2-5	1,07-4,84
	F	=	3,0±0,4	2,9-4	2,74-4,37
PROT (mg/dl)	M	=	7,7±.4	7-8,0	0,8-7,4
	F	=	7,0±0,0	7,2-8,9	7,0-8,0
ALB (mg/dl)	M	=	0,1±0,9	4,1-4,0	3,24-7,7

Appendix (1)

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Table ٧: List of normal values (appendix ١, ٢) for the common clinical biochemical test already published in the format in comparison with the present studied values.

Analyte(unit)	List of normal values	studied values
GLU(mg/dl)	٦٥-١١٠	٥٦,٤-١١٥,٦
CHOL(mg/dl)	١٥٠-٢٥٠	٩٢-١٩٦,٨
TG(mg/dl)	٦٥-١٨٠	٣٣,٧-١٧٢,١
HDL(mg/dl)	NA	١٤,٨-٤٨
UA(mg/dl)	٣-٧	٢-٥,٨
Blood urea (mg/dl)	٢٠-٤٥	٢٨,٨-٤٠,٨
CREAT(mg/dl)	٠,٧-١,٤	٠,٤-١,١
Ca(mg/dl)	٨,٥-١٠,٥	٨,٣-١٠,٢
PO٤(mg/dl)	٢,٥-٤,٥	٢-٤,٦
ALB(g/dl)	٣,٦-٥,٢	٣,٧-٦,٥
PROT(g/dl)	٦,٢-٨,٢	٦,١-٧,٩
TSB(mg/dl)	٠,٣-١	٠,٠٣-١
ALT(U/L)	٠-٢٠	٢,٥-٢١,٨
AST(U/L)	٠-١٥	٤,٤-٢٢,٧
ALP(U/L)	٣٠-٨٥	١٧-١٠٥,٥

Table ٨: Established reference ranges for some biochemical parameters in comparisons with Kuwait, Kenyans, American population as quoted in literature.

Analyte(unit)	sex	Kenyans	Kuwait	Iraq	American
ALT(U/L)	M	٠-٣٩	٠,٠-٣٢	٠-٢٦	١٠-٤٠
	F	٠-٤٠	٠,٠-٣٨	٥-١٧	٧-٣٥
AST(U/L)	M	٦-٤٠	١٣,٢-٣٢,٨	٢-٢٥	١٠-٤٢
	F	٣-٣٧	١١,٢-٣٠,٨	٦-٢٠	١٠-٤٢
ALP(U/L)	M	١٣-٢٠١	٣٢,٦-٩٥,٤	١٦-١١٢	٣٢-٩٢
	F	٥-٢٢٧	٣٢,٦-٩٥,٤	١٧-٩٩	٣٢-٩٢
PROT(g/L)	M	٥٧-٨٩	٦٣,٢-٧٨,٨	٥٨-٧٤	٦٤-٨٣
	F	٥٦-٨٨	٦٤,٢-٧٩,٨	٦٥-٨٥	٦٤-٨٣
ALB(g/L)	M	٢٩-٥٢	٣٦,١-٤٧,٩	٣٢-٦٧	٣٥-٥٠
	F	٢٨-٥٠	٣٤,١-٤٥,٨	٤٢-٦١	٣٥-٥٠
GLU(mmol/L)	M	٢,٨-٦,٨	٢,٧-٦	٢,١-٦,٣	٢,٧-٨,٣
	F	٢,٦-٧	٣,٨-٦	٢,١-٦,٢	٢,٧-٨,٣
PHOS(mmol/L)	M	٠,٥-٢	٠,٩-١,٤	٠,٥-١,٦	٠,٨٣-١,٤٨
	F	٠,٢-٢,٤	٠,٩-١,٤	٠,٩-١,٣	٠,٨٣-١,٤٨
CRAT(μmol/L)	M	٥٩-١٢٧	٦٣,٥-١١٤	٣٥-١١٩	٥٣-١١٥
	F	٥٤-١٢٢	٥٠,٥-٩٧,٥	٤٧-٨٤	٥٣-١١٥
Blood urea (mmol/L)	M	١,٥-٥,٩	٣,٤-٦,٧	٣,٥-٨	٢,٥-٦,٤
	F	١,٢-٦	٢,٤-٦,٧	٢,٥-٥,٧	٢,٥-٦,٤
UA(μmol/L)	M	١٢٠-٤٥٨	٢٢٠-٤٢٣,٩	١٨٠-٤٢٠	١٥٥-٤٢٨
	F	٨٩-٤١٥	١٥٥-٣٨٢,٧	١٢٠-٣٠٠	١٢٠-٣٦٠

Reference range for each analyte was calculated as the minimum and maximum value of 9٥% of the subjects using the formula; $\text{mean}(X) \pm 1,٩٦(\text{SD})$.

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Table 4: Gender difference of clinical biochemical parameters in the studied healthy adult age group.

parameters		
FBS(mg/dl)	٨٦,٣٧	٨٥,٧
CHOL(mg/dl)	١٤٣	١٤٥
TG(mg/dl)	٩٦,٦	٩٤,١
*HDL-Chol(mg/dl)	٢٨,٤	٣٤,٤
*UA(μmol/L)	٤,٤	٣,٥
*blood urea(mmol/L)	٥,٨	٤,٢
*CREAT(μmol/L)	٧٧,٥	٦٥,٨
CALICUM(mg/dl)	٩,٤	٩,٢
INORG.PO _٤ (mg/dl)	٣,٢	٣,٥
ALB(g/dl)	٥,١٢	٥,١٦
*PROT(g/dl)	٦,٦	٧,٥
TSB(mg/dl)	٠,٦	٠,٥٥
ALT(U/L)	١٣	١١,٣
AST(U/L)	١٣,٥٣	١٣,٥٨
ALP(U/L)	٦٤,٢	٥٨,٣

*significant difference
between male and female in the same age group.

TEST:	NORMAL VALUE (T.U)	CONV.F (T-S.I)	NORMAL VALUE (S.I.U)	CONV. F (S.I-T)
PROGESTERONE (males)	0.13 - 1.26 nanogram / ml	3.17	0.4 - 4.0 nanomol / l	0.315
PROGESTERONE(females):				
Follicular phase	0.06 - 1.26 nanogram / ml	3.17	0.2 - 4.0 nanomol / l	0.315
Ovulatory peak	0.08 - 1.2 nanogram / ml	3.17	0.25 - 3.8 nanomol / l	0.315
Luteal phase	2.5 - 25 nanogram / ml	3.17	8 - 78 nanomol / l	0.315
S.TOTAL PROTEIN	6.2 - 8.2 g / dl	10	62 - 82 g / l	0.1
S.GLOBULIN	2.4 - 3.7 g / dl	10	24 - 37 g / l	0.1
CSF - PROTEIN	15 - 40 mg / dl	0.01	0.15 - 0.4 g / l	100
U. PROTEIN	< 100 mg / day	1	< 100 mg / day	1
S.SODIUM	136 - 155 mEq / l	1	136 - 155 mmol / l	1
TESTOSTERONE (males)	2.8 - 8.2 nanogram / ml	3.46	9.7 - 28.4 nanomol / l	0.289
TESTOSTERONE (females)	0.1 - 1.0 nanogram / ml	3.46	0.34 - 3.4 nanomol / l	0.289
THYROXIN (T4)	4.5 - 12 microgam / dl	12.9	60 - 155 nanomol / l	0.0775
TRIIODOTHYRONIN (T3)	0.8 - 1.9 nanogram / ml	1.5	1.2 - 2.85 nanomol / l	+ 1.5
S.TRIGLYCERIDES	65 - 180 mg / dl	0.0133	0.86 - 2.4 mmol / l	75.3
S.URIC ACID	3.0 - 7.0 mg / dl	60	180 - 420 mmol / l	0.0166
U.URIC ACID	250 - 750 mg / day	0.06	1.5 - 4.5 mmol / day	16.6
S.UREA	20 - 45 mg / dl	0.166	3.3 - 7.5 mmol / l	6
U.UREA	15 - 30 g / day	16.6	250 - 500 mmol / day	0.06
IMMUNOGLOBULINS				
IgG	700 - 1800 mg / dl	0.01	7.0 - 18.0 g / l	100
IgA	90 - 450 mg / dl	0.01	0.9 - 4.5 g / l	100
IgM	50 - 220 mg / dl	0.01	0.5 - 2.2 g / l	100
HAEMATOLOGY				
H b - men	12 - 18 g / dl	10	120 - 180 g / l	0.1
H b - women	11.5 - 16.5 g / dl	10	115 - 165 g / l	0.1
PCV	0.4 - 0.45 l / l	100	40 - 45 %	0.01
MCHC	31 - 35 g / dl	10	310 - 350 g / l	0.1
WBC	4000 - 11000 / mm ³	0.001	4 - 11 x 10 ⁹ / l	1000
PLATELETS	150000 - 400000 / mm ³	0.001	150 - 400 x 10 ⁹ / l	1000
FIBRINOGEN	200 - 400 mg / dl	10	2 - 4 g / l	0.1

ملاحظة: هذه النتائج يستلزم بها، مع الاعتماد على الحدود الطبيعية المذكورة في حدة الفحص المستخدمة.



وزارة الصحة
دائرة الأمور الفنية
قسم المختبرات

LIST OF NORMAL VALUES FOR THE COMMON CLINICAL BIOCHEMICAL AND HAEMATOLOGICAL TESTS

TEST:	NORMAL VALUE (T.U)	CONV.F (T-S.I)	NORMAL VALUE (S.I.U)	CONV. F (S.I.T.)
BIOCHEMISTRY				
S.ALBUMIN	3.6 - 5.2 g / dl	10	36 - 52 g / l	0.1
S.ACID PHOSPHATASE	0 - 0.8 U / l	1	0 - 0.8 U / l	1
S.ALK. PHOSPHATASE	30 - 85 U / l	1	30 - 85 U / l	1
S.ALT (GPT)	< 20 U / l	1	< 20 U / l	1
S.AMYLASE	23 - 85 U / l	1	23 - 85 U / l	1
S.AST (GOT)	< 15 U / l	1	< 15 U / l	1
S.TOTAL BILIRUBIN	0.3 - 1.0 mg / dl	17.1	5 - 17 micromol / l	0.06
S.CALCIUM (total)	8.5 - 10.5 mg / dl	0.25	2.1 - 2.6 mmol / l	4
U.CALCIUM	100 - 350 mg / day	0.25	25 - 87 mmol / day	4
S.CHLORIDE	95 - 105 mEq / l	1	95 - 105 mmol / l	1
S.CHOLESTEROL	150 - 250 mg / dl	0.0259	3.87 - 6.47 mmol / l	38.7
S.COPPER	80 - 150 microgram / dl	0.1625	13 - 24 micromol / l	6.15
U.COPPER	10 - 50 microgram / dl	0.1625	1.6 - 8.1 micromol / l	6.15
S.CORTISOL (morning)	7.14 - 23.2 microgram / dl	28	200 - 650 nanomol / l	+ 28
S.CORTISOL (night)	< 300 microgram / dl	28	< 10.7 micromol / l	+ 28
S.CREATININE KINASE	20 - 230 U / l	1	20 - 230 U / l	1
S.CREATININE	0.7 - 1.4 mg / dl	88.4	62 - 124 micromol / l	0.0113
U.CREATININE	1.0 - 2.0 g / day	8.84	8 - 17 mmol / day	0.118
S.GAMMA G - T	5 - 85 U / l	1	5 - 85 U / l	1
S.GLUCEOSE (fasting)	65 - 110 mg / dl	0.0555	3.6 - 6.1 mmol / l	18
G.SF - GLUCOSE	40 - 70 mg / dl	0.0555	2.2 - 3.8 mmol / l	18
U.HMMA (VMA)	< 8 mg / day	5.05	< 40 micromol / day	0.2
S.IRON	70 - 180 microgram / dl	0.179	13 - 32 micromol / l	5.62
S.TIBC	250 - 400 microgram / dl	0.179	45 - 70 micromol / l	5.62
S.MAGNESIUM	1.8 - 2.4 mg / dl	0.411	0.7 - 1.0 mmol / l	2.4
U.MAGNESIUM	80 - 120 mg / day	0.411	33 - 50 mmol / day	2.4
S.INORGANIC PHOSPHATE	2.5 - 4.5 mg / dl	0.323	0.8 - 1.4 mmol / l	3.1
S.POTASSIUM	3.5 - 5.3 mEq / l	1	3.5 - 5.3 mmol / l	1

التعاون مع منظمة الصحة العالمية

مختبر الكيمياء الحيوية

طبع عام ٢٠٠٢

professionals understand the importance of reference intervals, many laboratories still do not have comprehensive data, especially ranges that are specific for their typical patient populations. There continues to be significant gaps in the available reference intervals as frequently intervals cited in the literature were obtained using older methodologies and instrumentation and cover a limited range of age groups or a relatively small number of samples⁽¹⁾ as shown in appendix^(1,2). There are no established reference ranges of biochemical parameters for our population but the Clinical Chemistry Laboratory relies on reagent manufacturers or published reference ranges which may not adequately represent our population. The objective of this study was therefore to establish reference ranges for some biochemical parameters for one group of ages and that is adult age group (٢٠-٤٠yr) which is considered as a reference range for other age group as far as human being last long time in

this age, moreover, most clinical biochemical analytes stay stable in this time period⁽³⁾. Correct interpretation of biochemical data for patients is critical in the correct diagnosis of

several illnesses⁽⁴⁾. In Iraqi adult, accurate reference ranges of these biological data that closely relate to the patients under investigation has not been reported previously and diagnosis is often based on data already obtained from subjects outside our community. This study reports sex specific reference ranges for some routinely requested for blood chemistry analytes from healthy subjects aged ٢٠ to ٤٠ year. The significantly higher reference range values for males compared to those of females in the established reference ranges for the Iraqi's adult population for (ALT), (BUN), (CREAT) and (UA) were also observed in the reference ranges in Kuwait population. Higher reference ranges for males compared to those of females were also

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observed for ALT and UA for the American adult population quoted in literature⁽¹¹⁾, compared to those of other adult population could be due to differences in either the lower reference limit or the upper reference limits or both⁽¹¹⁾. Differences in the lower and upper reference limits could be due to differences in the geographical location, methods and equipments used, sample size, posture, race, regional differences in the dietary

intakes of foods rich in these analytes, and genetics⁽¹¹⁾. Significantly higher reference range of creatinine in males relative to that of females with increasing age range in this study agrees with similar observation of Gardner and Cott⁽¹¹⁾. Higher creatinine levels in males than in females may be due to the greater muscle mass in males than females⁽¹⁴⁾. The higher UA in males relative to females could be explained by the menstrual cycle clearance rate in females than in males⁽¹²⁾. Lower ALP levels observed in males compared to females indicate that this enzyme varies with sex. Higher (HDL) values in female relative to male could be attributed to hormone variation⁽¹¹⁾.

CONCLUSION:

1. The study has established reference ranges for fifteen routinely analyzed biochemical parameters for the adult population. These reference ranges are different from those quoted in literature for other geographical regions. It is hoped that the results of this study will stimulate the establishment of reference ranges for other biochemical parameters in population and for other age group.
2. It is now coming the time to change the preset format into more advanced one that includes more parameters, recent national values, for both sexes, and for all age groups.

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