COMPARATIVE STUDY OF VITAMIN B12 AND HOLOTRANSCOBALAMIN OR ACTIVE B12 AS A MARKER FOR VITAMIN B12 DEFICIENCY AT DR GEORGE MUKHARI HOSPITAL

By

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DECLARATION

I, **Dr LM Murray**, hereby declare that this work, unless where acknowledged, is my own. It is being submitted in partial fulfillment of MMed in Chemical Pathology, in the Department of Chemical Pathology, School of Pathology, Faculty of Health Sciences at the University of Limpopo, Medunsa campus.

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Signature of candidate **Date**

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Abstract

Aim: This study was undertaken to compare the diagnostic sensitivity and specificity of total vitamin B12 analyses to active B12 (holoTC) analyses in a population of patients attending the Dr George Mukhari Hospital in Pretoria.

Methods: Routine serum folate, full blood count (FBC), thyroid function test, homocysteine, serum total vitamin B12 and active B12 analyses were performed on 30 samples.

Results: Serum folate was determined in all patients and 96% of the patients had a normal folate value. When looking at the FBC results it is important to note that three times as many males as females presented with anemia (36% versus 16%). Thyroid function tests were normal in 90% of patients. When the total vitamin B12 test was preformed only 10% of patients tested positive for vitamin B12 deficiency, in contrast to the active B12 analyses where 16% of patients tested positive for vitamin B12 deficiency. Both tests had a diagnostic sensitivity of 50%. The diagnostic specificity for total vitamin B12 was 93% in comparison with the 86% obtained by the active B12 analyses; when homocysteine was used as the true marker for vitamin B12 deficiency.

Conclusion: Diagnostic sensitivity was the same and the total vitamin B12 test's specificity was better in comparison to the active B12 analyses. Thus the active B12 assay cannot be recommended for routine use, since it has no benefit.

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CoA	Coenzyme A
CLIA	Clinical Laboratory Improvement Amendments
CV	Coefficient of variation
Da	Dalton
DGM	Dr George Mukhari
DNA	Deoxyribonucleic acid
dTMP	Deoxythymidine monophosphate
dUMP	Deoxyuridine monophosphate

DxI	Beckman Coulter UniCel DxI 800 Immunoassay System
e.g.	exempli gratia (for example)
FBC	Full blood count
FN	False negative
FP	False positive
FT3	Free triiodothyronine
FT4	Free thyroxine
g/dl	gram per deciliter
GC-MS	Gas chromatography mass spectrometry
GUM	Guide to the Expression of Uncertainty in Measurement
Hb	Hemoglobin
HC	Haptocobalamin
Hct	Hematocrit
H^+/K^+ ATPase	Hydrogen potassium adenosine triphosphate enzyme(ase)
HIV	Human immunodeficiency virus
holoTC	Holotranscobalamin
IF	Intrinsic factor
IQC	Internal quality control
LC-MS/MS	Liquid chromatography tandem mass spectrometry
LDH	Lactate dehydrogenase
MCV	Mean cell volume
MEIA	Microparticle enzyme immunoassay
mg	milligram

mIU/l	milli International Units per litre
MU	Measurement of uncertainty
ng/l	nanogram per litre
NHANES	National Health and Nutritional Examination Survey
NHLS	National Health Laboratory Services
NIST	National Institute of Standards and Technology
nmol/l	nanomol per litre
pmol/l	picomol per litre
RBC	Red blood cell
RDA	Recommended daily amount
RE	Random error
SD	Standard deviation
SE	Systematic error
SRM	Standard Reference Material
TC	Transcobalamin
TC-II	Transcobalamin II
TE	Total error
TFT	Tyroid function test
THF	Tetrahydrofolate
TN	True negative
TP	True positive
TSH	Thyroid stimulating hormone
µg	microgram

µg/100g	microgram per 100 gram
µg/day	microgram per day
µmol/l	micromol per litre
USA	United States of America
WHO	World Health Organization