SUMMARY OF TEST
The alkaline phosphatase is present in practically all tissues of the body, and it occurs at particularly high levels in intes- tinal epithelium, kidney tubules, bone, liver, and placenta. Although the precise metabolic function of the enzyme is not yet understood, it appears that the enzyme is associated with lipid transport in the intestine and with the calcification process in bone.

The present form in the sera of normal adults probably origi- nates mainly in the liver, with up to half the total activity coming from the skeleton. The respective contributions of these two forms to the total activity are markedly age dependent. Serum ALP measurements are of a particular interest in the investiga- tion of two groups of conditions: hepatic disease and bone disease associated with increased osteoblastic activi- ty. For many years, it was believed that ALP reaching the liver from other tissues (especially bone) was excreted into the bile and that the elevated serum enzyme activity found in hepatic disease was a result of a failure to excrete the enzyme through the bile. However, it is now known that the response of the liver to any form of biliary tree obstruc- tion is to synthesize more ALP. Intrahepatic obstruction of the bile flow also raises serum ALP, but usually to a lesser extent. Liver diseases that principally affect parenchymal cells, such as infectious hepatitis, typically also show only moderately elevated or even normal serum ALP levels. Among the bone diseases, the highest levels of serum ALP activity are encour- aged in Paget’s disease. Only moderate rises are observed in ostomalacia, the levels are slowly declining in response to vita- min D therapy. Primary hyperparathyroidism and secondary hyperparathyroidism are associated with slight to moderate elevations of ALP activity. Very high enzyme levels are present in patients with osteogenic bone cancer. Transient elevations may be found during healing of bone fractures. Physiological bone growth elevates ALP in serum, and this accounts for the fact that ALP activity increases in the sera of growing children one finds enzyme activity some 1.5 to 2.5 times that in normal adult serum. An increase of up to two to three times normal may be observed in women in the third trimester of pregnancy, although the interval is very wide and levels may not exceed the upper limit of the reference interval in some cases. The additional enzyme is of placental origin.
Methods of determining ALP activity have a long history, and numerous methods have had a more or less clinical use. The most popular of the chromogenic substrates for ALP is p-nitrophenyl phosphate. This ester is colorless, but the reaction product given the following results: sample 1 86.66 2.66 3.07 sample 2 222.40 5.74 2.58 Precision intra-assay (n=10) mean (UI) SD (UI) CV% sample 1 84.40 2.41 2.86 sample 2 222.40 5.74 2.58 inter-assay (n=20) mean (UI) SD (UI) CV% sample 1 86.66 3.66 3.07 sample 2 210.39 6.08 2.89 Methods comparison a comparison between Chema and a commercially availa- ble product gave the following results: ALP Chema = x ALP competitor = y n = 150 y = 1.03x - 2.57 UI $r^2 = 0.998$

WASTE DISPOSAL
This product is made to be used in professional laborato- ries. Please consult local regulations for a correct waste disposal. S65: dispose of this material and its container at hazar- dous or special waste collection point. S57: use appropriate container to avoid environmental contamination. S61: avoid release in environment. Refer to special instruc- tions/safety data sheets.

REFERENCES

QUALITY CONTROL AND CALIBRATION
It is suggested to perform an internal quality control. For this purpose the following human based control sera are available:

GN 0500 CH QUANTINORM CHEMA 10 x 5 ml with normal or close to normal control values
QP 0500 CH QUANTIPATH CHEMA 10 x 5 ml with pathological control values.
If required, a multiparametric, human based calibrator is available.

TEST PERFORMANCE
Linearity the method is linear up to 3000 UI. If a ΔA/min of 0.500 is exceeded, it is suggested to dilute sample 1+9 with saline and to repeat the test, multiplying the result by 10.

Sensitivity/limit of detection (LOD) the limit of detection is 5.2 UI.

Interferences no interference was observed by the presence of: hemoglobin ≤ 400 mg/dl bilirubin ≤ 40 mg/dl lipids ≤ 900 mg/dl

MATERIALS REQUIRED BUT NOT SUPPLIED

PRINCIPLE OF THE METHOD
The enzyme alkaline phosphatase (EC 3.1.3.1, orthopho- spheric-monooester phosphohydrolase) hydrolyzes the 4- NPP to release 4-nitrophenol, under alkaline conditions. This ester is colorless, but the reaction product gives the following results:

sample 1 86.66 2.66 3.07 sample 2 222.40 5.74 2.58 Precision intra-assay (n=10) mean (UI) SD (UI) CV% sample 1 84.40 2.41 2.86 sample 2 222.40 5.74 2.58 inter-assay (n=20) mean (UI) SD (UI) CV% sample 1 86.66 3.66 3.07 sample 2 210.39 6.08 2.89 Methods comparison a comparison between Chema and a commercially availa- ble product gave the following results: ALP Chema = x ALP competitor = y n = 150 y = 1.03x - 2.57 UI $r^2 = 0.998$

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REFERENCES

MANUFACTURER
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SYMBOLS
| IVD | for in vitro diagnostic use only |
| LOT | lot of manufacturing |
| REF | code number |
| storage temperature interval | expiration date (year/month) |
| warning, read enclosed documents | read the directions |