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510(k) Summary

- Trade name: Prostatic Acid Phosphatase Reagent Test
- Common name: PAP test kit
- Classification name: CFR 862.1020 Acid phosphatase (total or prostatic) test system

This applications identifies the Abbott PAP EIA test kit as the legally marketed device to which we claim equivalence.

Since Gutman *et al* reproted[1] in 1936 that abnormally high levels of acid phosphatase (ACP) and partially, prostatic acid phosphatase (PAP), were found in prostatic cancer patients, ACP and PAP have been used as indexes in the diagnosis and monitoring of prostatic cancer.

Previously, L- (+) tartaric acid inhibition method was used to determine the level of PAP[2]; however , it has been known to inhibit ACP of other origins. Thus sufficient sensitivity and organ specificity were not achieved until the development of RIA[3] and EIA[4] methods. Despite their accuracy, RIA and EIA require a substantial amount of time to administer and are intricate to perform. Other problems with these methods include the prerequisite of specialized equipment.

This method uses anti-human PAP mouse monoclonal antibodies to inhibit PAP activity which results in much higher specificity than is obtained with tartaric acid inhibition method. With this test kit, the PAP is completely eliminated from ACP in calculating the level of PAP. High sensitivity composite substrate 2,6-doichloro-4-acetylphenyl phosphate (DCAP-P) is used, making it simple and fast to use with general purpose automated analyzers[5].

BIBLIOGRAPHY

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5. Katayama, K. *et al. Clin. Chem.* 38:979, 1992