

A Proposal of Guideline Development of Quality Assurances for Veterinary Blood Diagnostic Test in Korea

Jin-San Moon

Veterinary Pharmaceutical Management Division, Animal and Plant Quarantine Agency, Gimcheon 177, Republic of Korea

The use of medical devices for veterinary diagnostic test has recently increased for the demand for diagnostics that is essential in determining prognosis, identifying disease stages, monitoring treatment, and assessing the spreading as health services. In particular, blood hematology, chemistry, and gas analyzer has rapidly expanded in veterinary diagnostic test. Therefore, they should require the quality assurances (QA) to secure the confidence of test. This study was proposed the guideline development of QA for veterinary blood diagnostic test in Korea. Most of these instruments registered as veterinary medical devices were hematology, chemistries, and gas analyzer. The registration of instrument and reagent for hematology and chemistry test from the APQA by July 2017 were 37 & 13 products from eight & six countries, respectively. The domestic market size of veterinary hematological testing apparatus and reagent reported from KAHPA in 2016 was estimated to be approximately 108 and 88 billion won per year, respectively. The blood diagnostic tests were mainly performed in dog, cat, horse and cattle. These findings indicate that the registration and sales of the blood diagnostic test have gradually increased, and have been further growing bigger due to the increasing demand for healthcare services in Korea. However, the guidelines and general information of QA for these instruments were little limited in veterinary medicine. Recently, the Quality and Laboratory Standards committee of the American Society for Veterinary Clinical Pathology has produced guidelines to QA for point-care testing (POCT) and portable blood glucose meter use in veterinary medicine. These guidelines are aimed at veterinarians and veterinary technicians seeking to improve management POCT, and provide a minimum standard for maintenance of POCT instruments in the veterinary or research setting. This study suggested that the development of these guidelines of QA for blood diagnostic test should be made in the future in Korea.

Keyword: Veterinary Diagnostics, Veterinary medical devices, Quality Assurances

Funding Source: This work was supported by a grant from Animal and Plant Quarantine Agency.

Disclosure Statement: None of the authors have any conflicts of financial interest to declare.