

Role of the Pharmacist in the Distribution of Diagnostic Products And Laboratory and Diagnostic Testing

INTRODUCTION

The Saskatchewan College of Pharmacists acknowledges the potential benefits of diagnostic products. Used properly, these products permit earlier detection of health problems and closer monitoring of existing conditions while also encouraging increased patient involvement in personal health. Used improperly, diagnostic products are of limited value and may even be detrimental to the patient's health. Therefore, SCP recognizes the role of the pharmacist in distributing diagnostic products and assisting the patient to understand the proper use of such products.

SCP also recognizes the diagnostic role of the physician, and the role of other health-care personnel in conducting laboratory and diagnostic tests. The role of the pharmacist should compliment, and not interfere with or infringe upon the statutory role of other health-care personnel.

Increasing interest in pharmacy sponsored disease state screening programs requires clear understanding of the role of the pharmacist in both the distribution of diagnostic products, and in laboratory and diagnostic testing. Therefore, the role of the pharmacist should be consistent with the pharmacist's knowledge and training and be subject to statutory limitations.

OBJECTIVES

To describe the role of the pharmacist in the distribution of diagnostic products intended for patient use outside of conventional laboratory and health care facilities recognizing the traditional and contemporary role of the pharmacist, the legal and liability position of the pharmacist and the public interest.

DEFINITION

Diagnostic Products - Products which may or may not be associated with a medical device that contain agents, drugs or chemicals designed for patient use outside of conventional laboratory and health care facilities for the purpose of testing, identifying, self-diagnosing, screening or monitoring a human condition or disease.

GUIDELINES

1. The pharmacist may sell diagnostic products where such products contain adequate written instructions for the patient and where the product has been approved for sale in Canada.
2. The pharmacist should be familiar with the contents of the diagnostic product and the test procedures and protocol established by the manufacturer.
3. The pharmacist should be available to counsel the patient on the proper use of the diagnostic product. This includes advising the patient on the proper procedures for conducting the test and how to properly interpret the test results.
4. Where the nature of the diagnostic product demands, the pharmacist should be sufficiently trained to, in turn, train the patient on the proper use of the product.
5. The pharmacist, or another qualified health care professional, may conduct, administer or interpret a diagnostic test in the pharmacy for demonstration purposes only. This means that the pharmacist, or other health care professional, may collect a personal specimen, or specimen from the patient, apply the specimen to the testing device and/or express an opinion on the meaning of the result to demonstrate to the patient on how to use the device properly. For example, the pharmacist, or a registered nurse hired for the purpose, may take a sample of blood from the patient to show the patient how to use a home blood glucose monitoring device.
6. The pharmacist may supervise the performance and interpretation by the patient of a diagnostic test performed in the pharmacy.
7. The pharmacist should advise the patient to consult a physician where a self-diagnosis, or absence thereof, requires confirmation.

8. The examination or analysis of a specimen taken or collected from a human body for the purposes of screening for any health-related purpose is considered to be a "test" within the meaning of The Medical Laboratory Licensing Act. Any site where such tests are performed must be licensed and meet personnel, instrumentation and testing proficiency criteria. Therefore, the pharmacist responsible for a screening program as described above should ensure that the site where the program is to be conducted is licensed by Saskatchewan Health. The contact information is below.

The pharmacist shall ensure that that no patient or customer is charged a fee for any test carried out in the pharmacy.

9. Regional Health Authorities are responsible for the delivery of most laboratory services and receive funding through their global budgets for these services. Many of the tests which may be under consideration for performance in a pharmacy are likely included in that funding. INR testing, for example, is the responsibility of RHAs. Therefore, prior to submitting an application for a license, pharmacists should consult with their RHA if they wish to discuss funding or operational issues that may include opportunities for continuity of care, and test information, collection and disclosure (i.e. reporting)

For further information contact:

Laboratory Licensing Manager
Saskatchewan Health
3475 Albert Street
Regina, Saskatchewan S4S 6X6
(306)787-4539
(306)787-3423

DIAGNOSTIC PRODUCTS

Include, but are not limited to:

Cholesterol Testing Products

Cholestech LDX System

Urine Glucose Testing Products

Chemstrip UG 5000/k

Keto-Diastix

Labstix

Clinistix

Clinitest

Diastix

Tes Tape

Blood Glucose Testing Products

Chemstrip bG

Dextrostix

Visidex II

BM-Test-BG

Glucostix

Blood Glucose Testing Devices

Accucheck II

Glucoscan 3000

One Touch II

Pregnancy Test Kits

Answer Plus

Advance

Discover 2

Acu Test

Confidelle

Tespack hCG - Urine

Urine Ketone Test Kits

Chemstrip K

Ketostix

Other Test Kits

Hemastix - Blood in urine

Hematest - Blood in feces

Combistix - Protein, glucose, and
pH in urine.

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