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MEDICAL LABORATORY TESTING IS ONE OF THE MOST EFFECTIVE AND PROVEN METHODS FOR PREVENTING AND DETECTING DISEASE. (VISION FOR A BETTER TOMORROW)

Medicine

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ABSTRACT

Laboratory blood studies can reveal a little information about organ systems throughout the body. The amount of blood taken for a laboratory test is not harmful. Human body manufactures a couple of milliliters of new blood every day. Blood studies may give information about the levels of sodium, potassium, calcium and other chemicals. Presence of certain enzymes and information about the coagulation characteristics, levels of sugar, urea, cholesterol, alcohol, protein, and other drugs of patients' blood sample. Diagnosing diseases and disorders requires highly developed skill on the part of the physician or other medical professional .Usually the diagnosis calls for systematic use of and diagnostic aids, various tests, and instruments and machines. Quality systems are the mainstay of clinical laboratory management.

KEYWORDS

Nucleic acid-based tests, rapid diagnostic test (RDT), MRI,CAT,ELISA (Enzyme linked immunosorbent assayHA(Hemagglutination)CF (Complement fixation) FAST(Falcon assay screening test),DOT-ELESA,RDTS(Rapid antigen detecting system),LIPS(Luciferase Immunoprecipitation system, PCR(Polymerase chain reaction),RT-PCR (Real time Polymerase chain reaction),LAMP (Loop mediated isothermal Amplification)

INTRODUCTION

Introduction Medical diagnosis is the process of determining which disease or condition explains a person's symptoms and signs (1). It is most often referred to as diagnosis with the medical context being implicit. The diagnosis is the first step in the process of therapeutics prescription. There are several means of diagnosis of diseases including symptomatic, molecular and genomics (2). The conventional way of clinical diagnosis is still in practice provide first and basic information regarding disease and causative agents as well. Diagnostic tests play a major role in the clinical care of patients with infectious diseases, including detection of specific pathogens, the discovery of new pathogens, determining appropriate therapy, monitoring response to therapy, assessing prognosis, and disease surveillance (3). Despite the increased use of rapid tests and the availability of molecular and proteomics-based tests, diagnostics are not being integrated into clinical care optimally. Integration is influenced by the clinical syndrome, the availability of and access to appropriate diagnostics, the place of service, and the experience and knowledge of the healthcare provider (4). The goal of the chapter is to increase awareness of the current and potential value of infectious diseases diagnostics for patient care and public health and to promote further development of needed diagnostics. The credit goes to Antonie van Leeuwenhoek (1632–1723), the "father of the microscope," changed the course of infectious diseases when he enabled the visualization of the microbial world, a world no one had imagined (5). Since then, the goal of infectious diseases diagnostics has been to detect the source of the infection and enable an appropriate response. Now, we have better stains, better microscopes, and novel agar media types, standard microscopy and culture methods have not changed dramatically in more than a century. Recently, new technologies have brought great advances in infectious diseases diagnostics. The field of clinical microbiology is currently in transition, and standard-of-care testing is now a hybrid of old and new methodologies (6). The evolution of infectious diseases diagnostics has resulted from advances in chemistry, immunology, molecular biology, engineering, automation, and nucleic acid amplification. It is now possible to determine the specific etiology of a patient's infectious disease in the hospital, clinic, office, remote village, or even a patient's home (7). With automation and highly multiplexed assays, individual 14 pathogens can be readily identified in a wide variety of specimen types including blood, urine, tissue, mucosal swabs, cerebrospinal fluid (CSF), respiratory secretions, and stool samples. The modern diagnostic is quick, robust and precise in finding cause for candidate disease and allow ease in data studies (8). Conventional diagnostics approaches One of the most frequent reasons for performing clinical laboratory tests is to support, confirm, or refute a diagnosis of a disease that is suspected based on other sources such as the patient's history, physical examination findings, and imaging studies (9, 10). The questions that need to be considered are which clinical laboratory tests could be of value in supporting, confirming, or excluding the clinical impression? What is the most efficient test-ordering strategy? If a test result is positive, will that confirm the clinical impression or even formally establish the diagnosis? If negative, does that disprove the clinical suspicion, and what further testing or approach is needed? What are the known sources of false-positive and false-negative results, and how does one recognize these? Staining and Examination Using a Microscope One basic and very old method is the identification of a microorganism simply by looking at it under a microscope. Most samples are treated for stains. Stains are special dyes that color the microorganisms, causing them to stand out from the background (11). Some microorganisms have a distinctive size, shape, and stained color that enable doctors to recognize them. However, many microorganisms look alike and cannot be distinguished using a microscope. Also, there must be enough of them, and they must be large enough to be seen with a microscope. For example, viruses cannot be identified using a microscope because they are too small (11). For bacteria, doctors often first use Gram stain (a violet-colored stain). Bacteria are classified as follows: Gram-positive (they look blue because they retain the violet Gram stain) Gram-negative (they look red because they do not retain the stain) 15 Culture of Microorganisms Usually, a sample contains too few microorganisms to see using a microscope or to be identified using other tests. Thus, labs usually try to grow (culture) the microorganism in a laboratory until there are enough to identify. A sample is taken from an area of the person's body likely to contain the microorganism. Samples may include Blood Sputum Urine Stool Tissue Cerebrospinal

fluid Mucus from the nose, throat, or genital area The sample is placed in a dish or in a test tube that contains specific nutrients to encourage the growth of microorganisms. Different nutrients are used depending on which microorganisms doctors suspect. Often, doctors add substances to the test tube to stop the growth of microorganisms that do not cause the disease doctors suspect (12). Many microorganisms, such as the bacteria that cause urinary tract infections or strep throat, can easily be grown in culture. Some bacteria, such as the bacteria that cause syphilis, cannot be cultured at all (13). Other bacteria, such as those that cause tuberculosis, can be cultured but take weeks to grow. Some viruses can be cultured, but many cannot. Antibody tests Antibody tests are usually done on a sample of the infected person's blood. They also can be done on samples of cerebrospinal fluid or other body fluids. Antibodies are substances produced by a person's immune system to help defend against infection .They are produced by certain types of white blood cell when these white blood cells encounter a foreign substance or cell (14). It typically takes several days to produce the antibody. An antibody recognizes and targets the specific foreign 16 substance (antigen) that triggered its production, so each antibody is unique, made for a specific type (species) of microorganism. If a person has antibodies to a particular microorganism, it means that the person has been exposed to that microorganism and has mounted an immune response (15). However, because many antibodies remain in the bloodstream long after an infection has resolved, finding antibodies to a microorganism does not necessarily mean the person is still infected. The antibodies may remain from a previous infection. Antigen tests Antigens are substances that can trigger an immune response in the body. Microorganisms have antigens on their surface and inside them. Antigen tests detect the presence of a microorganism directly so that doctors can diagnose an infection quickly, without waiting for a person to produce antibodies in response to the microorganism (16). Also, these tests can be used in people whose immune system cannot produce many antibodies, such as people who have recently had bone marrow transplantation or who have AIDS. To do antigen tests, doctors take a sample from a person and mix it with a test antibody to the suspected microorganism. If there are antigens from that microorganism in the person's sample, they attach to the test antibody (17). Different methods can be used to detect the antigen-antibody combination. But whatever method is used, the presence of the antigen means that the microorganism is present and probably is the cause of the infection. Modern diagnostics approaches Nucleic acid-based tests If a microorganism is difficult to culture or identifies by other methods, doctors can do tests to identify pieces of the microorganism's genetic material. This genetic material consists of nucleic acids: deoxyribo nucleic acid (DNA) or ribonucleic acid (RNA). The polymerase chain reaction (PCR) is an example of this type of test (18). The PCR technique is used to produce many copies of a gene from a microorganism, making the microorganism much easier to identify. Each genetic test is specific to only one specific microorganism. That is, a genetic test for hepatitis C virus detects only that virus and not any other. 17 Thus, these tests are done only when a doctor already suspects a particular disease. Most nucleic acid-based tests are designed to identify the presence of a microorganism (called qualitative testing) (19). However, a few of these tests can measure the amount of genetic material present (called quantitative testing) in certain such as HIV and hepatitis C, and thus determine how severe the infection is. Quantitative tests can also be used to monitor how well treatment is working. Nucleic acid-based tests can sometimes be used to check the microorganisms for genes or gene mutations that make the microorganism resistant to a drug (20). However, these tests are not completely accurate because not all resistance mutations are known. Thus, tests cannot check for all the genes for resistance that may be present. Also, these tests are expensive, not widely available, and available for only a few microorganisms. Non-nucleic acid-based identification tests These tests are so named because they are not based on identifying the microorganism's genetic material, which consists of nucleic acids (DNA and RNA). For example, tests can be done to identify the substances that the microorganism can grow in or grows best in when it is cultured. Enzymes produced by the microorganism (which help the microorganism infect cells or spread through tissues faster) (21). Other substances in the microorganism (such as proteins and fatty acids) that help identify it. Impact on human health Modern medicine relies extensively on the clinical laboratory as a key component of health care. It is estimated that in current practice, at least 60–70% of all clinical decisions rely to some extent on a laboratory result. For many diseases, the clinical laboratory provides essential diagnostic information (22). As an example, the histopathologic analysis provides basic information about histologic type and classification of tumors and their degree of invasion into adjacent tissues. Microbiologic testing is required to identify infectious organisms and determine antibiotic susceptibility. For many common diseases, expert groups have produced standard guidelines for diagnosis that rely on defined clinical laboratory values, e.g., blood glucose or hemoglobin A1C levels form the basis for diagnosis of diabetes mellitus; the presence of specific serum antibodies is 18 required for diagnosis of many rheumatologic diseases; and serum levels of cardiac markers are a mainstay in diagnosis of acute coronary syndromes. A rapid diagnostic test (RDT) is a medical diagnostic test that is quick and easy to perform. RDTs are suitable for preliminary or emergency medical screening and use in medical facilities with limited resources (23). Malaria RDTs detect specific antigens (proteins) produced by malaria parasites that are present in the blood of infected individuals. Some RDTs detect a single species (either P. falciparum or P. vivax), some detect multiple species (P. falciparum, P. vivax, P. malariae and P. ovale) and some further distinguish between P. falciparum and non-P. Falciparum infection, or between specific species. Blood for the test is commonly obtained from a finger-prick and results are available within 15-30 minutes (24). Though there are variations among the more than 200 malaria RDT products on the market, the principles of the tests are similar. With the use of conventional diagnostic methods and new cutting-edge modern tools in clinical diagnosis the following outcomes are 1. Rapid clinical diagnosis 2. Robust tests and higher reproducibility 3. Readymade diagnostic kits 4. Ready to use 5. Ease in sample processing 6. Digital output 7. Ease of data interpretation 8. Low title volume 9. Patient compliance 10. Low cost

History and Mechanism

Patient safety agenda is gaining momentum in the health care systems of all developed countries. However, adverse event detection systems and initiatives to reduce error rates in medicine are in their infancy. Laboratory services play a crucial role in both individual and population-based healthcare, and clinical laboratories use many different methods to reduce errors, ensure patient safety, and improve quality including quality control procedures, quality assurance programs, accreditation of laboratories and certification of education programs. Considerable advances in analytical techniques, laboratory instrumentation, information technologies, automation and organization have granted an exceptional degree of analytical quality over the past 50 years. This, in turn, has resulted in a significant decrease in error rates, analytical error rates in particular. There is consolidated evidence that nowadays, most laboratory errors fall outside the analytical phase, and that pre- and post-analytical processes are more vulnerable to error than analytical processes

MAJOR ADVANCES AND DISCOVERIES

The old and new diagnostic tests to diagnose pathogenic parasites , viruses,bacteria are observing parasites,ova,cysts, blood smear, MRI,CAT,ELISA (Enzyme linked immunosorbent assay),HA(Hemagglutination),CF (Complement fixation) FAST(Falcon assay screening test),DOT-ELESA,RDTS(Rapid antigen detecting system),LIPS(Luciferase Immunoprecipitation system, PCR (Polymerase chain reaction),RT-PCR (Real time Polymerase chain reaction),LAMP (Loop mediated isothermal Amplification) ets are the major diagnostic tests.

WHERE THE RESEARCH GO NEXT ?

The clinical diagnosis is a first and most crucial step in the process of finding therapeutics for a disease. There are several approaches are being used in clinical diagnosis including routine laboratory tests as conventional methods and also rapid and robust modern methods. Both the approaches have their significance in the clinical diagnosis of a disease. The conventional approaches largely depend on microscopy and staining of microorganism responsible for disease while modern methods are based on molecular signature and findings. In 19 the current scenario, there is a need for rapid and robust diagnostics as global disease burden is prevailing. At the same time, there is the continuous emergence of new and complex infectious pathogens, and hence early diagnosis provides ease in disease management. Recently, use of nanotechnology and enzyme-based diagnostic became popular and shown satisfactory results. The use of diagnostic become an

integral part of modern medicine and involves molecular biology and cutting-edge bioengineering as well. The integration of information technology in diagnostic is an added advantage to minimize time and ensure precise data interpretation.

Current Debate

Some common reasons of not getting quality and reliable results are 1. Lack of commitment on part of staff performing the tests 2. Poor management and supervision 3. Poor understanding of quality assurance concepts 4. Analysts do not understand the concepts of assay principles 5. Reagents used are not high quality 6. Poor quality of instruments 7. Procedures are not followed as recommended 8. Under staff leads to high error rate. 9. Lack of equipment. 10. Mislabeling blood sample. 11. Un labeling blood sample.

References

1- Ross AGP, Bartley PB, Sleigh AC, Olds GR, Li Y, Williams GM, McManus DP. Schistosomiasis. N Eng J Med 2002;346:1212-9.
2- Gryseels B, Polman K, Clerinx J, Kestens L. Human schistosomiasis. Lancet 2006;368:1106-18.
3- Steinmann P, Keiser J, Bos R, Tanner M, Utzinger J. Schistosomiasis and water resources development: systematic review, meta-analysis, and estimates of people at risk. Lancet Infect Dis 2006;6:411-25.
4- King CH, Dickman K, Tisch DJ. Reassessment of the cost of chronic helminthic infection: a meta-analysis of disability-related outcomes in endemic schistosomiasis. Lancet 2005;365:561-9.
5- King CH, Dangerfield-Cha M. The unacknowledged impact of chronic schistosomiasis. Chronic Illness 2008;4:65-79.
6- Mas-Coma S, Valero MA, Bargues MD. Climate change effects on trematodiases, with emphasis on zoonotic fascioliasis and schistosomiasis. Vet Parasitol 2009;163:264-80
7- Leshem E, Meltzer E, Marva E, Schwartz E. Travel-related schistosomiasis acquired in Laos. Emerg Infect Dis 2009;15:1823-6.
8- Ross AG, Vickers D, Olds GR, Shah SM, McManus DP. Katayama syndrome. Lancet Infect Dis 2007;7:218-24.
9- Wynn TA, Thompson RW, Cheever AW, Mentink-Kane MM. Immunopathogenesis of schistosomiasis. Immunol Rev 2004;201:156-67.
10- Burke ML, Jones MK, Gobert GN, Li YS, Ellis MK, McManus DP. Immunopatho genesis of human schistosomiasis. Parasite Immunol 2009;31:163-76.
11- Carod-Artal FJ. Neurological complications of Schistosoma infection. Trans R Soc Trop Med Hyg 2008;102:107-16.
12- Ferrari TC. Involvement of the central nervous system in the schistosomiasis. Mem Inst Oswaldo Cruz 2004;99:59-62.
13- McManus DP, Gray DJ, Li YS, Feng Z, Williams GM, Stewart D, et al. Schistosomiasis in the Peoples' Republic of China: the era of the Three Gorges Dam. Clinic Microbiol Rev 2010;23:442-66.
14- Katz N, Chaves A, Pellegrino J. A simple device for quantitative stool thicksmear technique for schistosomiasis mansoni. Rev Inst Med Trop Sao Paulo 1972;14:397-400. 21
15- Oliveira LM, Santos HL, Gonçalves MM, Barreto MG, Peralta JM. Evaluation of polymerase chain reaction as an additional tool for the diagnosis of lowintensity Schistosoma mansoni infection. Diagn Microbiol Infect Dis 2010;68:416-21.
16- Wichmann D, Panning M, Quack T, Kramme S, Burchard GD, Grevelding C, Drosten C. Diagnosing schistosomiasis by detection of cell-free parasite DNA in human plasma. PLoS Negl Trop Dis 2009;3:e422.
17- Gomes LI, Dos Santos Marques LH, Enk MJ, de Oliveira MC, Coelho PM, Rabello A. Development and evaluation of a sensitive PCR-ELISA system for detection of Schistosoma infection in feces. PLoS Negl Trop Dis 2010;4:e664.
18- Ellis MK, Li Y, Hou X, Chen H, McManus DP. sTNFR-II and sICAM-1 are associated with acute disease and hepatic inflammation in schistosomiasis japonica. Int J Parasitol 2008;38:717-23.
19- Bergquist R, Johansen MV, Utzinger J. Diagnostic dilemmas in helminthology: what tools to use and when? Trends Parasitol 2009;25:151-6.
20- Chand MA, Chiodini PL, Doenhoff MJ. Development of a new assay for the diagnosis of schistosomiasis, using cercarial antigens. Trans R Soc Trop Med Hyg 2010;104:255-8.
21- Stothard JR, Sousa-Figueiredo JC, Standley C, Van Dam GJ, Knopp S, Utzinger J, et al. An evaluation of urine-CCA strip test and fingerprick blood SEA-ELISA for detection of urinary schistosomiasis in schoolchildren in Zanzibar. Acta Trop 2009;111:64-70.
22- Doenhoff MJ, Cioli D, Utzinger J. Praziquantel: mechanisms of action, resistance and new derivatives for schistosomiasis. Curr Opin Infect Dis 2008;21:659-67. [PubMed]
23- Cioli D, Pica-Mattoccia L. Praziquantel. Parasitol Res 2003;90:S3-S9. [PubMed]
24- Hou XY, McManus DP, Gray DJ, Balen J, Luo XS, He YK, et al. A randomized, double-blind, placebo-controlled trial of safety and efficacy of combined praziquantel and artemether treatment for acute schistosomiasis japonica in China. Bull World Health Organ 2008;86:7 88-95.