

The Role of General Laboratory Examination Package accomplished in Private Labs in detection of subtle diseases in Iraqi population

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Introduction

Laboratory investigations are a medical procedure that involves testing a sample of blood, urine, or other substance from the body. Laboratory tests can help determine a diagnosis, plan treatment, check to see if treatment is working, or monitor the disease over time. A screening test tells a provider and a person more testing may be needed, and a diagnostic test gives more definite information. Each test helps a person decide how to proceed with the life (1).

Early detection of subclinical diseases allows the implementation of care pathways that can slow the progression of the disease, improving clinical outlook and quality of life, as well as the avoidance of situations that might cause worsening of body functions and acute injuries, such as administration of certain drugs. This medical scrutiny is a primary preventive health measure for the early diagnosis of diseases and prevention of undue morbidity and mortality. Staying physically active and conscious about health can help prevent or delay certain diseases, including some cancers, heart diseases and diabetes (2).

Much has been debated about General Laboratory Examination (**GLE**) in recent years which represent an exercise in preventive medicine. Those in favor of such screening of laboratory investigations point to the economic and social advantages of early detection and better diagnosis of disease to an individual and the community. The opponents of this type of blanket screening point to the dubious diagnostic value of many of the abnormal results found and the impracticability of making laboratory screening generally available even if it was shown to be of definite value (3).

Despite contrary evidence, most primary care providers believe that an annual laboratory examination detects subclinical illness. This is partly driven and shaped by factors such as apparent perception of benefit, patient expectation, employer requirement, and insurance industry protocols. Healthcare institutions in Iraq do not offer structured health checkup “packages” for routine screening of common diseases. Unnecessary and inappropriate screening tests cause financial and resource burden as it must be done in private costly labs (4).

Evidence suggests that only certain diseases are amenable for screening in an asymptomatic adult. It is recommended that physicians should abandon recommending these general panels in favor of a more selective approach to prevent health problems individualized to every unique patient. Accordingly, it has become necessary to pay attention to and focus on early detection of disease through effective and evidence-based examination programs and periodic health checks for specific age groups, in order to help in reducing the burden of disease and provide health services coverage to a larger segment of the population to achieve comprehensive health coverage (5).

The use of any diagnostic test should be guided by certain principles. (a) Whether the test is a good diagnostic tool in terms of sensitivity, specificity, simplicity, cost, safety, and acceptability. (b) Whether the burden of the suffering caused by a particular disease in terms of morbidity and mortality warrants early detection and diagnosis. (c) Finally, before undertaking any screening, the physician should consider if the disease diagnosed by said test has a good guideline for therapy (6).

the demand for periodic medical examination or preventive examination services is weak in many developing countries and is sub-optimal, although the Eastern Mediterranean countries face a large burden of communicable and chronic diseases, which increases the need for their interest in the periodic medical examination (7).

In fact, one study demonstrated that panel chemistry testing led to fewer return visits of patients to clinics and substantially lower costs than

with selective testing. Panel testing is also much more informative and more convenient to patients who need not be subjected to multiple blood samplings. Another advantage in panel testing has been cost: the direct charges to the patient or payer are often lower when profile testing is done than when a selected smaller group of tests is ordered (8).

Aim of this study:

- To investigate the clinical effectiveness of the GLE package accomplished in a lot of private labs in Iraq in screening subtle diseases.
- Determination of inappropriate tests included in the panel.
- To develop a package contain the most clinically useful tests which could consequently contribute to policy implications for medical examinations .

MATERIALS AND METHODS

This observational study was conducted over a period of 4 months in four Iraqi governorates Baghdad, Basrah, Babil, Karbala'a. Eighty nine (89) private labs were checked in a regular questionnaire. Questionnaire include the average total no. of general test package in the month, no. of subtests in each general package, the cost of the package, and the most frequent abnormal tests recorded.

The general components of the package; mostly all the labs accomplish the following subtests for checkup: **Urinalysis:** color, turbidity, pH, specific gravity, protein, glucose, occult blood, nitrites, **Hematology:** WBC count total and differential, RBC count, hemoglobin, hematocrit, RBC indices (MCV, MCH, MCHC), platelet count, **Chemistry:** total protein, lipid profile (TG, total cholesterol, HDL, LDL, VLDL), glucose, liver functions tests (AST, ALT, ALP, TSB), urea , creatinine, uric acid, CRP, HbA1c, H.pylori.

The usefulness of the test assessed according to the criteria of (The Japan Society of Clinical Pathology (JSCP)). The clinically useful test is the test that give newly established diagnosis corresponding to patient's clinical state after interpretation of test results (8). Inappropriate test is

defined as the test for which the risks of harm to the patient clearly outweigh the potential benefits (9).

Results and Discussion:

After collecting data it appears that the average no. of general tests/month in Baghdad come in the first order (1452), Basrah comes next (181), Karbala'a comes in the third stage (77), and Babil comes last (13). This variation may be due to difference in economic states among the chosen governorates (10).

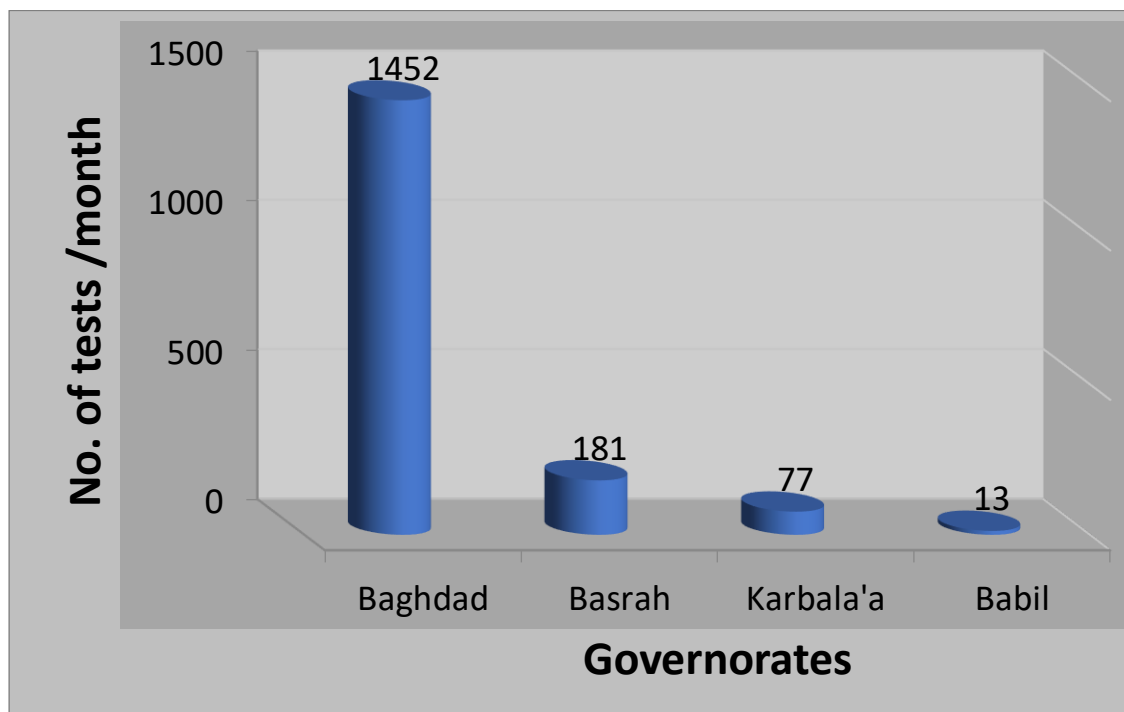


Figure (1): The mean no. of general tests accomplished in each governorate.

The mean no. of subtests in each package was found to be **12±4.5** test/ package. **5.57±2.1** tests was found to be abnormal which means 50% of these random tests were found to be clinically useful & give an aid for the physician to get early diagnosis to occult disease.

The mean cost of the general test panel is **40.3±17.4 IQD**; according to mean financial employee of Iraqi population it could be gotten by about half of Iraqis in normal conditions. A mean of **19.6±9.3 IQD** was the cost of

abnormal tests; which represent 50% of the cost this represent cost effective test as more than 35% useful test make the panel cost effective (8) .

The most frequent abnormal tests seen in checkup general package were listed in Figure (2). **The abnormal lipid profile (LP)** which may be due mainly to obesity which is regarded as epidemic health problem in Iraqi population because of the genetic susceptibility of Iraqis to obesity as reported by M. Almyah et al (11). Other factor may be the cigarette smoking habit which was prevalent in Iraqi society in a ratio of more than 50% as it has a big impact on lipid profile as reported by WW Mustafa et al (12). However the unhealthy food habits and the sedentary life style may have the main contributor to this abnormality as reported by M. Crovetto et al (13).

Abnormal CBC seen later in the frequency of abnormal tests. Most of these abnormalities crowded on high Hb or low Hb which interpreted as polycythemia and anemia respectively. Polycythemia may be due mainly to the high prevalence of cigarette smoking as it was reported by W. Waleed et al (14). Another factor which may be prevalent recently is the administration of male sex hormones for body building as reported by SJ Ohlander (15). Anemia mostly seen in those with poor food habits and old ages due to consumption of modern junk food, the unscientific diet programs, occult bleeding for long time in GIT specially in old age people as presented by S Kaur (16).

Low vit.D level frequently seen in those general tests may be attributed to the changes currently appeared in western design of the houses compared to the previous eastern design characterized by central house yard full of sunlight, accompanied by the disappearance of gardens from homes as they converted to additional buildings either for commercial purposes, or residential ones. The bad unsecured situation in the country may lead to minimize the people's traffic in the parks for promenading. The wide distribution of veiling between women (for religious reasons) may results in this significant low Vit.D level among women which agreed with AL-Turki HA *et al* [140]. Nevertheless, the role of veiling in vitamin D deficiency

status in females in present study is doubtful, because an approximate rate of deficiency among men was observed (96%). In addition to backtrack in the number of working women and the subsequent homebound with aging may contribute to this frequent low level seen (17).

High percent of HbA1c frequently seen in the healthy checked persons may be due to preclinical stages of T2DM caused by the genetic susceptibility, bad food habits, dyslipidemia, sedentary life style and other factors related to obesity . Iron deficiency anemia may be resulted in elevated % of HbA1c as the decline in the Hb level might lead to increase in the glycated fraction at a fixed glucose level, because HbA1C is measured as a percentage of total Hb (18). Or it may be related to a hidden undiagnosed cancer as reported by A Goto (19) or could be due to aging as shown by J Roth (20).

Abnormal GUE seen in these packages mainly presented as crystals and UTI; both of these problems may be caused by Low urine volume, Low fluid intake, High intake of animal protein, Positive family history of stone formation, Hot and arid climate. People working outdoors in hot weather have an increased risk of stone formation due to excessive fluid loss from sweating (21).

The frequent appearance of H.pylori; Helicobacter pylori are urease producing organisms gram- negative that are found throughout the world and produce chronic gastritis, it may also predispose patients to develop duodenal ulcers (22) . About half of the world's population is estimated to be infected with this pathogen. However, the reported infection rates vary between different regions, with greater prevalence in developing countries than in developed countries. On the other hand, in the Eastern Mediterranean region, an H. pylori prevalence of up to 80% was reported (23). This high prevalence of this pathogen in Eastern Mediterranean region put Iraqi population in the risky groups of high prevalence infection. Different methodology for confirmation of H. pylori infection has a characteristic sensitivity and specificity and cost-effectiveness which may influence an investigation's outcome as reviewed by M (24).

Abnormal LFT were less frequently seen which may be due mostly to hidden viral hepatitis infections, or congenital defect causing subclinical liver problems as reviewed by C Irene et al (25).

Abnormal frequent TSH level revealed both subclinical hypothyroidism and subclinical hyperthyroidism (26). Almost one-third of the world's population live in areas of iodine deficiency despite major national and international efforts to increase iodine intake, but iodine deficiency is an emerging. In iodine-deficient foods, most persons with thyroid disorders have autoimmune disease, ranging from primary atrophic hypothyroidism to Hashimoto's thyroiditis to thyrotoxicosis caused by Graves' disease. The prevalence of spontaneous hypothyroidism is between 1 and 2%, and it is more common in older women and ten times more common in women than in men. The prevalence of hyperthyroidism in women is between 0.5 and 2% and is ten times more common in women than in men. Epidemiological studies suggest that 1% of men and 5% of women have thyroid nodules detected clinically and that the frequency increases with age and in iodine-deficient populations. Controversy exists as to whether healthy adults from screening for thyroid disease as the prevalence of unsuspected overt thyroid disease is low, but a substantial proportion of subjects tested will have evidence of thyroid dysfunction, with approximately 10% with subclinical hypothyroidism and 1% with subclinical hyperthyroidism. Gender, dietary factors, iodine deficiency, family history, diabetes and x-ray radiation were reported as risk factors associated with different type of thyroid diseases (27).

Highly frequent cases of hyperuricemia (HUA) is a metabolic syndrome, which not only correlates with the development of gout, but is also related with obesity, hypertension, and glucose and lipid metabolism disorders (28). Epidemiology studies showed an increasing trend in the prevalence of hyperuricemia and gout with the changes in diet structure. Low vegetable consumption, high WC, TP, and serum urea levels, passive smoking, snoring, and high meat consumption were independent risk factors for hyperuricemia (29). All of these factors were prevalent in Iraqi society.

Low serum ferritin represent the first stage of normal Hb anemia, this stage generally has no symptoms, although, patients develop iron deficiency (16). According to World Health Organization [4], globally, anemia affects 1.62 billion people, which corresponds to 24.8% of the population. The unhealthy diet programs adopted by a lot of people in a try to get the perfect posture, in addition to inadequate vitamin C intake, and diets rich in inhibitors of iron absorption, and associated H.pylori infection, all of these factors and others represent risk factors to have low serum ferritin level.

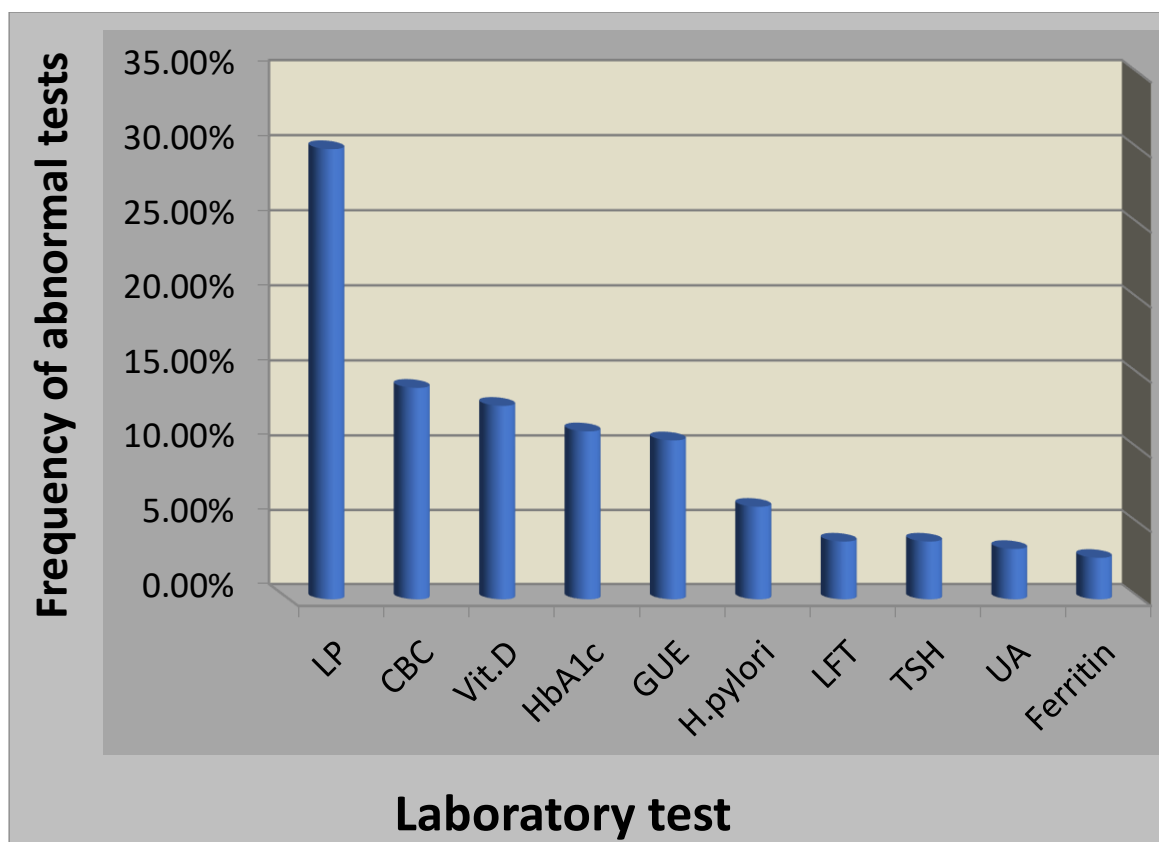


Figure (2): The most frequent abnormal laboratory tests

Tests done and do not have clinical effectiveness: include urea and creatinine as these parameters were imperfect indices of GFR; do not affected unless the renal function is largely affected where the patient was no long healthy (30). It is more clinically useful to be represented as urea creatinine ratio in result report (30). C-reactive protein (CRP) does not represent a value in this panel as it is a blind marker can be substituted by WBC count, it can be used as a prognostic marker rather than diagnostic

as its low normal level represent the healing state (31). Plasma glucose level does not represent clinical effective test as the HbA1c can represent its level for three months ago (32).

Conclusion

- The general test package accomplished by a no. of private labs in Iraq is clinically useful and cost effective.
- A no. of tests must be omitted from the package as they did not give a clinical usefulness
- A no. of tests must be added or modified to get its clinical usefulness and cost effectiveness.

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