# LABORATORY ALGORITHM FOR SCREENING TESTING OF PREGNANT WOMEN

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Knowledge of the algorithm for examining pregnant women to identify fetal developmental defects is important for clinicians and district pediatricians. This allows them to better assess the condition of newborns, predict the child's developmental rate, and formulate preventive measures. Knowing the regulatory documents, methodology, and diagnostic capabilities of prenatal diagnosis methods for the fetal condition, the district pediatrician can help motivate future mothers to perform screening, especially if there are already children with developmental defects in the family [1,2].

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Prenatal diagnosis is a complex of medical measures and diagnostic methods aimed at detecting morphological, structural, functional, or molecular disorders in the intrauterine development of the fetus. This branch of medicine lies at the intersection of several specialties-obstetrics and gynecology, genetics, ultrasound diagnostics-and is an important part of practical healthcare. Therefore, it is necessary to train specialists with diverse knowledge who can take a comprehensive approach to this issue, properly counsel the patient, and determine the tactics for managing the pregnancy [3,4,5,6].

Methods of prenatal diagnosis are divided into direct (when the fetus itself or fetal material is examined directly) and indirect (when conclusions about the fetus's condition are drawn from the results of maternal studies). In addition, there are noninvasive and invasive methods.

Any prenatal diagnosis begins with collecting the mother's medical history, and preliminary conclusions can already be drawn at this stage.

A classic example is determining the risk of Down syndrome in the fetus based

on the mother's age. The genealogical method involves analyzing data on heredity in the future child's family and compiling a family tree. Using this method, for example, the risk of monogenic pathology can be assessed. Laboratory and instrumental examination of the mother is also part of prenatal diagnosis. It reflects the mother's health status, which directly affects the health of the future child, for whom the mother's body serves as the environment. Today, it is believed that the conditions in which the fetus was in the mother's womb determine epigenetic modifications that influence the development of chronic diseases in the child later in life. For instance, it is known that if the mother had hyperglycemia during pregnancy, the child has an increased risk of developing type 2 diabetes, obesity, and cardiovascular diseases throughout subsequent life. Analysis of embryo-specific proteins (PAPP-A, hCG, AFP) is an important part of prenatal screening and belongs to indirect diagnostic methods.

Although these proteins are typically produced only during pregnancy, in some cases they can be produced outside of pregnancy, for example, in certain oncological diseases.

Conclusions about the risk level of giving birth to a child with pathology, based on the analysis of embryo-specific proteins, are only approximate. Noninvasive direct methods include ultrasound examination (USG), cardiotocography (CTG), and magnetic resonance imaging (MRI) of the fetus. Additionally, noninvasive prenatal screening based on obtaining fetal (placental) DNA from the mother's blood can be considered among noninvasive direct methods. Invasive methods for obtaining fetal material include chorionic villus aspiration (CVS), placentobiopsy, amniocentesis, cordocentesis, and fetal tissue biopsy.

Methods for analyzing fetal material can vary-karyotyping, chromosomal microarray analysis, searching for mutations associated with monogenic diseases, biochemical analyses, and even histological examination (for example, in cases of suspected bullous epidermolysis). Fetoscopy is also an invasive method, but due to advances in ultrasound diagnostics, it is rarely used today [7,8,9,10].

Biochemical screening of the first trimester can be performed from 8-9 weeks, but from an organizational standpoint, it is more efficient to take blood on the same day as the ultrasound, so that the risk level can be calculated on the same day (the "one-day clinic" concept). In the first trimester, two markers are used for analysis-PAPP-A test and beta-hCG. PAPP-A (pregnancy-associated plasma protein) is secreted by trophoblast and decidual cells throughout pregnancy and regulates intercellular contacts between trophoblast cells and decidual tissue. In chromosomal abnormalities, PAPP-A levels decrease. Beta-hCG is detectable in the blood of a pregnant woman as early as 10-12 days after fertilization and reaches its maximum at 11-12 weeks of gestation. In Down syndrome, this marker increases; in Edwards and Patau syndromes, it decreases [11,12,13,14,15].

Biochemical markers change at different gestational ages and are evaluated in MoM (multiple of the median)-the measured value is divided by the median norm for that gestational age. In the norm, values should be between 0.5 and 2.0 MoM. However, the greatest significance lies not in individual markers, but in the overall risk calculated using computer algorithms that account for all indicators. The first-trimester prenatal screening report includes medical history data, ultrasound results, and biochemical marker levels. At the end, the "expected risk" of chromosomal abnormalities is stated. The expected risk consists of the baseline and individual risk. Baseline risk is the age-related risk, which is the same for all women of the same age. For example, for all women aged 35, the risk of trisomy 21 (Down syndrome) is 1:385 [16,17,18].

Individual risk is the risk calculated taking into account not only age, but also other anamnestic data, ultrasound results, and biochemical marker levels [19,20,21,22,23,24].

The sensitivity and specificity of this method are 85-90% and 95%, respectively. When the entire screening methodology is followed, it is quite effective, but both false-positive and false-negative results are possible. In the case of a false-negative result, a chromosomal abnormality in the fetus may be missed. With false-positive results, the number of unjustified invasive interventions increases-among women referred for invasive diagnostics based on first-trimester screening results, chromosomal abnormalities in the fetus are present in no more than 25-30% [22,23,24].

Thus, screening results can be influenced by incorrect gestational age calculation, ultrasound physician qualifications, medication intake, maternal somatic diseases, or the threat of spontaneous miscarriage. It should be remembered that first-trimester prenatal screening is an indirect diagnostic method, so its capabilities are limited. Even with strict adherence to examination timing, ultrasound and biochemical research methodology, only about 80% of pregnancies with a Down syndrome fetus fall into the high-risk group. Therefore, further improvement of prenatal screening for major aneuploidies is required.

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