**Can women rely on results of pregnancy tests?**

***(Prague, July 30, 2014)*** **Inspectors of the Technical Inspection Department of the CTIA focused on inspections of pregnancy tests, i.e. in vitro diagnostic devices for self-testing, in order to check functioning of these medical devices intended for use by laics at home. Laboratory analysis concerned 15 pregnancy tests collected in the retail market. Despite the fact that according to the results of a referential laboratory all collected samples correctly detected early stage of pregnancy, i.e. at latest on the day of expected menstruation, cases can occur when gravidity is not noticed when the test is used too early. Pregnancy test reliably confirms or disproves pregnancy only on the day of expected menstruation and negative result gained within self-testing before this day can be misleading. Therefore it is necessary that women follow recommendation in the package leaflet attached to the pregnancy test and visit a physician who would confirm or disprove pregnancy.**

The Czech Trade Inspection Authority included the above mentioned action in the plan of inspections based on submission and queries from the public relating to the effectiveness of pregnancy tests offered in the Czech market. Samples of 15 types of pregnancy tests from various manufacturers were purchased within the inspection action, especially in e-shops and drugstores. Pregnancy tests sampled by the CTIA inspectors were handed over to an accredited referential laboratory. Inspectors bought kits for 50 determinations within each test in order to ensure objectivity of the evaluation. Laboratory tests proved that all inspected tests correctly – i.e. at latest on the day of expected menstruation – detected early stage of pregnancy. However, referential laboratory alerted that accompanying documentation can contain misleading information concerning detectable level of chorionic gonadotropin (hCG) in the values of 10 IU/l or 25 IU/l because the detectability depends on a number of factors, e.g. on urine concentration and its composition, conditions under which the test is carried out and so forth.

Pregnancy tests are intended for self-testing and use by laics at home. The products are classified as in vitro diagnostic medical devices in which conformity with applicable legal regulations shall be assessed before they are placed on the market. Their functionality is an obligatory part of the conformity assessment, meaning that manufacturer or importer has to prove and provide that the particular product can diagnose what is declared in the accompanying leaflet. The test can correctly diagnose an early stage of pregnancy if used at correct time – which can be a problem in some cases with regard to the fact that it is not possible to accurately determine the moment of conception. When considering the fact that a sperm lives for several days, pregnancy can only be reliably recognized after 12 days from fertilization. The idea that it is possible to immediately detect correct results with the help of pregnancy test is not realistic.

The risk within use of pregnancy test doesn’t originate in incorrect operation of the product, but rather in illiteracy of its users who may wrongly think that negative result of a pregnancy test as detected on second or third day after sex is correct. Every woman who has suspicion of pregnancy should carry out the gravidity test first on the day of presumed menstruation and subsequently – according to the recommendation of the pregnancy test’s accompanying leaflet – go to a specialized medical facility who can confirm or disprove pregnancy detected by the test.

**Inspections of accompanying and technical documentation**

Within the inspection action, the Czech Trade Inspection Authority aimed at whether manufacturers, authorized representatives, importers, and distributors of pregnancy tests for domestic use (i.e. in vitro diagnostic medical devices, further on referred to as IVD) comply with requirements of the Act No. 22/1997 Coll. on Technical Requirements for Products as specified in the Government Order No. 453/2004 Coll. on Technical Requirements for in vitro diagnostic medical devices. Based on the inspection action inspections were carried out at manufacturers and distributors of pregnancy tests. CTIA focused on inspection of accompanying documentation and labelling of products at distributors and on inspection of compliance with procedures concerning conformity assessment in the determined way at manufacturers. Inspections were carried out at the total of 26 subjects, including 2 manufacturers, 3 importers, and 21 distributors.

Pursuit to the Government Order No. 453/2004 Coll. on Technical Requirements for in vitro diagnostic medical devices, each IVD has to be equipped with information necessary for its safe and correct use and data identifying the manufacturer. These data shall be directly on the product if applicable or on packaging and also in instructions for use. In case of IVD products, instructions for use shall be provided to the user together with the product or attached in a packaging of one or more products. All user information shall be in Czech.

In total 15 types of pregnancy tests collected at 3 distributors and 11 importers were inspected. Other 12 commercial subjects involved in distribution of the diagnostic device were inspected in the consequence of assessment of samples and with the aim to inform entities that place them on the market or first distributors on the territory of the Czech Republic.

Shortcomings concerning labelling of products, accompanying and technical documentation, or other obligatory marking were detected within two types of the total of 15 inspected pregnancy tests:

* product *Dipstrip* was not labelled with required CE marking and was not marked in compliance with the applicable government order
* products *Gravitest - těhotenský test 2v1* was not labelled in compliance with the applicable legal regulations

**Detected shortcomings and imposed measures**

Shortcomings were detected concerning 2 products types at 2 distributors. These related to labelling and marking of products and accompanying and technical documentation.

Inspection of labelling, marking, accompanying and technical documentation saw the following shortcomings:

* Importer failed to ensure that each IVD product included in packaging contains data necessary for identification of an authorized representative and information that the product is used for self-testing. Inspectors didn’t find any information about the last date of revision of instructions for use in annexed instructions for use in Czech and the product was not equipped with CE marking together with annexed identification number of notified person participating in procedures of conformity assessment. On-the-spot fine amounting to 5,000 CZK and measure of remedy were imposed for these breaches. The inspected subject removed the detected shortcomings within determined deadline.
* Importer placed on the market a selected product IVD in which conformity was not assessed in compliance with the applicable government order. Instructions for use didn’t contain any data of identification of authorized representative and the Czech translation of instructions for use didn’t contain the same information as the original instructions for use provided by the manufacturer. Administrative proceedings will be launched with the inspected company for the detected breaches. The entity fulfilled the imposed measures of remedy and removed the detected shortcomings in the determined deadline.
* Based on conclusions by referential laboratory CTIA asked 6 distributors and 3 importers for opinion on the above mentioned value of detected level of chorionic gonadotropin (hCG) from 10 IU/L, respectively from 25 IU/L and explanation of how functional capability for this value was checked (in compliance with section 21, par. 3 of the Regulation of the European Parliament and of the Council (CE) No. 765/2008).

**The following pregnancy tests for domestic use met the laboratory assessment of functionality:**

**Woman secret „Baby“**

**Fremund- jednorázový test těhotenský hCG močový test**

**BENU quick pregnancy test**

**Apotheke- GRAVITEST 12**

**Clearblue compact**

**PEPINO pregnanci test dipstrip**

**Dr. Max Lady MAX test 2 v 1**

**Domácí těhotenský test Predictor Early**

**ROSSMANN facelle**

**AXIOM SET**

**RapiClear**

**Rychlý těhotenský test Prenatal comfort**

**CEMIO Gravitest direct**

**INTIMED DipStick hCG Quick test**

**VitalX těhotenský test plus**