



## Pregnancy tests for family planning

### Description

Low-cost, accurate urine pregnancy tests are a simple tool that can be used to rule out pregnancy for some women and help increase access to same-day provision of family planning methods.\* Guidance from the World Health Organization (WHO) indicates that, for hormonal contraceptives, a woman can initiate a method if her health care provider is “reasonably certain she is not pregnant.”<sup>1</sup> Because many family planning providers in developing countries rely on the presence of menses to rule out pregnancy among clients, women who are not menstruating at the time they visit the clinic are routinely denied same-day provision of family planning.<sup>2,3</sup> Studies show that anywhere from 5 to 50 percent of non-menstruating women are denied services,<sup>4,5</sup> even though several studies have shown that very few of these women are actually pregnant.<sup>6,7</sup> Non-menstruating women are usually told to return to the clinic during their next menses, but without family planning these women remain at risk of unplanned pregnancy in the interim.

Pregnancy tests can help remove these barriers. They can be used to rule out pregnancy when a woman is amenorrheic, such as when she is postpartum but not protected from pregnancy by the Lactational Amenorrhea Method (LAM),<sup>8</sup> or when she is amenorrheic as a result of using injectable contraception and returns late for a re-injection.<sup>9</sup> Also, pregnancy tests should be used to rule out pregnancy when women come to the clinic after they have missed their menses.

In addition to ruling out pregnancy for women seeking family planning, pregnancy tests may offer other reproductive health benefits. For example:

- For women seeking health services because they want to know their pregnancy status, these contacts may be an ideal “teachable moment” to offer follow-up family planning counseling and provision.
- For women who are using progestin-only hormonal contraceptives, pregnancy testing can reassure those who worry that they are pregnant when they experience the normal side effect of amenorrhea.<sup>10</sup>

- Early access to pregnancy tests was associated with earlier access to antenatal care or abortion services in a study in South Africa.<sup>11</sup>

### Efficacy

#### *Proper use and accuracy*

Two types of urine pregnancy tests are currently available. Both types employ test strips that detect human chorionic gonadotropin (hCG) levels in the urine to determine the likelihood of pregnancy. In the first type, the user holds a test strip in the urine stream to capture a mid-stream sample. In the second type, the user captures a urine sample in a cup and then dips a test strip into the cup (known as a “dip strip test”). With both types, the user only has to wait a few minutes before viewing the results window on the test strip, which indicates whether the user is likely pregnant. Most tests also have a control indicator to indicate whether the test is working properly. Dip strip tests are less expensive than the mid-stream tests and are typically used in low-resource settings. Blood tests for pregnancy status are also available and very effective, but their cost remains prohibitive in most developing countries.

Both types of urine pregnancy test have similar accuracy rates, and they are both very accurate when used correctly and after enough time has passed since fertilization. Instructions included with commercially available tests indicate that a client should wait until after the expected date for the next menses has passed before testing. Some over-the-counter tests claim up to 99 percent accuracy one day after the missed menses. However, studies have shown this claim to be exaggerated<sup>12,13,14</sup> and estimate that the accuracy is closer to 90 percent on the first day after missed menses. Accuracy increases as more time elapses after the missed menses, and the authors of one study estimate 97 percent accuracy seven days after the missed menses.<sup>12</sup> Some tests may take as long as two weeks after the day of expected menses to be effective.

The body begins producing the hCG hormone as soon as a fertilized egg attaches to the uterine wall (usually 6 to 12 days after fertilization), and hCG levels continue increasing

\* A urine pregnancy test will not be effective in determining pregnancy status in all cases, including for women who are between two normal menses. It is recommended that the Pregnancy Checklist be used by family planning programs in conjunction with pregnancy tests (see the “Current program use” section of this brief for more information).

as the pregnancy progresses. The variability in the accuracy of pregnancy tests is often due to the natural variations in the timing between when women ovulate and when the fertilized egg attaches to the uterine wall.<sup>12</sup> Therefore, when a woman arrives at the clinic between two menstrual periods, she may be already pregnant, but it is too early for the urine pregnancy test to detect it (i.e., hCG levels are not high enough yet).<sup>\*\*</sup> Depot medroxyprogesterone (DMPA) study trials have shown approximately 2 percent of women fall into this category.<sup>15</sup> The accuracy of the test is also related to the sensitivity of the test strip used; higher sensitivity means that the test strip can detect lower levels of hCG in urine and therefore can detect pregnancy earlier than less sensitive strips. Other variables affecting accuracy of the urine pregnancy test include user error (whether the instructions were followed correctly), taking certain medicines, and drinking excessive amounts of water.

### *Efficacy in increasing access to same-day provision of family planning*

A recent study in Zambia demonstrated that, by providing free pregnancy tests at government family planning clinics, the number of women denied contraceptive services was substantially reduced.<sup>10,16</sup> In intervention sites where pregnancy tests were available, the proportion of non-menstruating women who were denied a method dropped from 15 percent at baseline to 4 percent at follow-up, while the percentage remained unchanged at 17 percent in the control group. This means that non-menstruating clients were more than four times more likely to be denied a method in control sites where no pregnancy tests were offered. A similar study in Ghana did not show the same effect; however, in this setting, the number of clients who were denied a method was low at baseline, and stock-outs of family planning methods were reported to be an issue.<sup>10,16</sup>

### Current program/sector use

Few low-resource countries include pregnancy testing as part of routine family planning services because these tests are perceived as too expensive. However, the price of highly accurate dip strip tests has decreased significantly, and programs and donors can now purchase these tests for less than US\$0.10 per test.<sup>17</sup>

It is important to note that, even as pregnancy tests become more widely available in family planning programs in developing countries, there is still an important role for the simple, low-tech Pregnancy Checklist to help

providers rule out pregnancy.<sup>18,19</sup> The Pregnancy Checklist includes a series of questions based on the criteria for ruling out pregnancy from the WHO Selected Practice Recommendations, and the tool has been validated and used in multiple countries.<sup>5,6</sup> Although pregnancy tests are relatively inexpensive, they are not free, so a preferred protocol is to take a history and use the checklist first, and then use a pregnancy test only when necessary. For example, if a woman is amenorrheic because she is postpartum or she has discontinued use of progestin-only injectables, the checklist should be used first and, if it fails to rule out pregnancy, a pregnancy test should be used. In addition, both tools have clinical limitations. Urine pregnancy tests cannot detect pregnancy earlier than a week or two after a missed period and therefore should not be used with women presenting between two normal menses; in these cases, the checklist should be used. If a woman has already missed her menstrual period, a pregnancy test should be used instead of the checklist.

In addition, according to WHO, no known harm occurs to either a pregnant woman or a fetus from exposure to hormonal family planning methods.<sup>\*\*\*,20</sup> Therefore, the benefits of increased access to these methods likely outweigh any potential risks associated with denial.<sup>16</sup> Given the high maternal mortality and morbidity rates in many low-resource countries, every effort should be made to provide effective contraception on the same day that a woman presents for contraceptive services.

### Manufacturer/supplier

There are many manufacturers and suppliers of pregnancy tests located in high-, middle-, and low-income countries, including Canada, China, India, South Korea, Taiwan, and the United States. Typically, country programs that want to purchase pregnancy tests are advised to work with a third-party distributor or international procurement group.

### Registration status

Pregnancy tests are often available with a CE mark, a mandatory conformity mark for medical devices used by European Union member states. If pregnancy tests have a CE mark or the manufacturer meets equivalent standards set by the International Organization for Standardization, they often do not require any additional regulatory approval at the national level. Some countries do require registration for pregnancy tests before importation; in these cases, the process is usually simple and straightforward.

\*\* Certain tests, such as a quantitative blood pregnancy test, can measure the exact level of hCG in the blood. While these tests can detect pregnancy a few days after implantation and before the first missed menstrual period, they are expensive as noted above, require laboratory services, and are not routinely used to diagnose pregnancy.

\*\*\* In case of the IUD, it is very important to rule out pregnancy because inserting an IUD in a woman who is already pregnant may result in septic miscarriage, which is a serious complication.

## Public-sector price agreements

Urine pregnancy dip strip tests are available for less than US\$0.10 per test.<sup>17</sup> Typically, prices are dependent on the volumes procured.

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