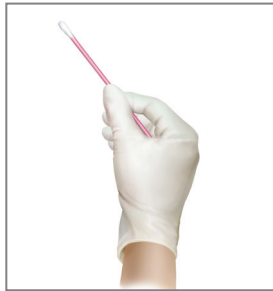


Aptima[®] Multitest Swab Specimen Collection Kit

Clinician collection procedure guide

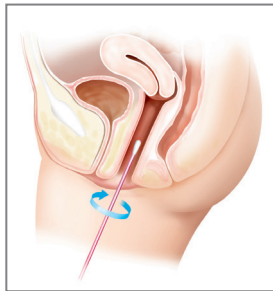
Collection for vaginal swab specimens



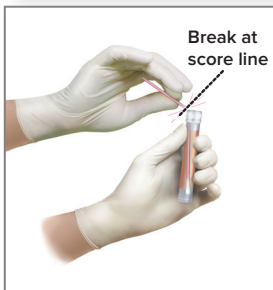
Partially open the swab package and remove the swab. Do not touch the soft tip or lay the swab down. **If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Multitest Swab Specimen Collection Kit.** Hold the swab, placing thumb and forefinger in the middle of the shaft covering the black score line. Do not hold the shaft below the score line.

Swab specimen collection guide for:

- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (NG)
- *Mycoplasma genitalium* (MG)
- *Trichomonas vaginalis* (TV)
- Bacterial vaginosis (BV)
- Candida vaginitis (CV)



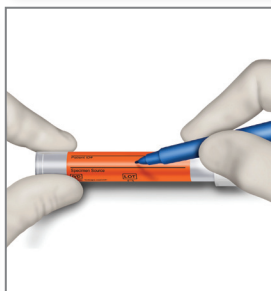
Carefully insert the swab into the vagina about 2 inches (5 cm) past the introitus and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the vaginal walls so that moisture is absorbed by the swab. Withdraw the swab without touching the skin.



Break at score line



While holding the swab in hand, unscrew the tube cap. Do not spill the tube contents. **If the tube contents are spilled, discard and replace with a new Aptima Multitest Swab Specimen Collection Kit.** Immediately place the swab into the transport tube so the black score line is at the top of the tube. Align the score line with the top edge of the tube and carefully break the shaft. The swab will drop to the bottom of the vial. Discard the top portion of the shaft.



Tightly screw the cap onto the tube. When collecting multiple specimens from the same patient, the tube label provides a specimen source field for unique identification for the specimen location.



Hologic provides this collection procedure guide as a general informational tool only; it is not an affirmative instruction or guarantee of performance. It is the sole responsibility of the clinician to read and understand the appropriate package insert and comply with applicable local, state and federal rules and regulations.

hologic.com | diagnostic.solutions@hologic.com | +1.888.484.4747

DS-01552-001 Rev. 005 © 2019 Hologic, Inc. All rights reserved. Hologic, The Science of Sure, Aptima and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. This information is intended for medical professionals in the U.S. and other markets and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshows, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, please contact your Hologic representative or write to diagnostic.solutions@hologic.com.

Aptima® Multitest Swab Specimen Collection Kit



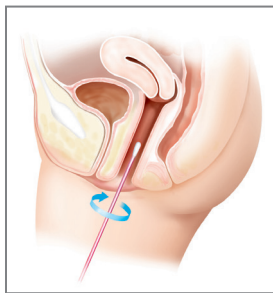
Patient collection procedure guide

Collection for vaginal swab specimens

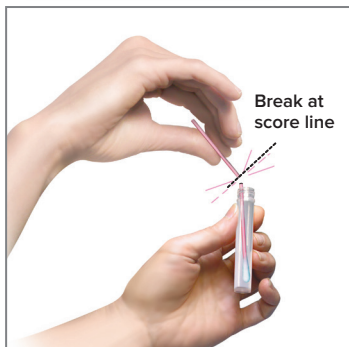


Wash hands before starting. If you have any questions about this procedure, please ask your healthcare provider.

Partially peel open the swab package and remove the swab. Do not touch the soft tip or lay the swab down. **If the soft tip is touched, laid down or dropped, request a new Aptima Multitest Swab Specimen Collection Kit.** Hold the swab, placing thumb and forefinger in the middle of the shaft over the black score line.



Carefully insert the swab into the opening of the vagina, about 2 inches (5 cm), and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the vaginal walls so that moisture is absorbed by the swab. Withdraw the swab without touching the skin.



While holding the swab in your hand, unscrew the tube cap. Do not spill the tube contents. **If the tube contents are spilled, request a new Aptima Multitest Swab Specimen Collection Kit.** Immediately place the swab into the transport tube so the black score line is at the top of the tube. Align the score line with the top edge of the tube and carefully break the swab shaft. The swab will drop to bottom of the vial. Discard the top portion of the shaft.



Tightly screw the cap onto the tube.
Return the tube as instructed by your healthcare provider.

Hologic provides this collection procedure guide as a general informational tool only; it is not an affirmative instruction or guarantee of performance. It is the sole responsibility of the clinician to read and understand the appropriate package insert and comply with applicable local, state and federal rules and regulations.

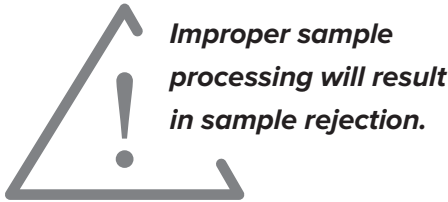
hologic.com | diagnostic.solutions@hologic.com | +1.888.484.4747

DS-01553-001 Rev. 003 © 2017 Hologic, Inc. All rights reserved. Hologic, The Science of Sure, Aptima and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. This information is intended for medical professionals in the U.S. and other markets and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshows, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, please contact your Hologic representative or write to diagnostic.solutions@hologic.com.

Aptima[®] Multitest Swab Specimen Collection Kit

Specimen processing guide

Collection for multitest swab specimens



Swab specimen collection guide for:

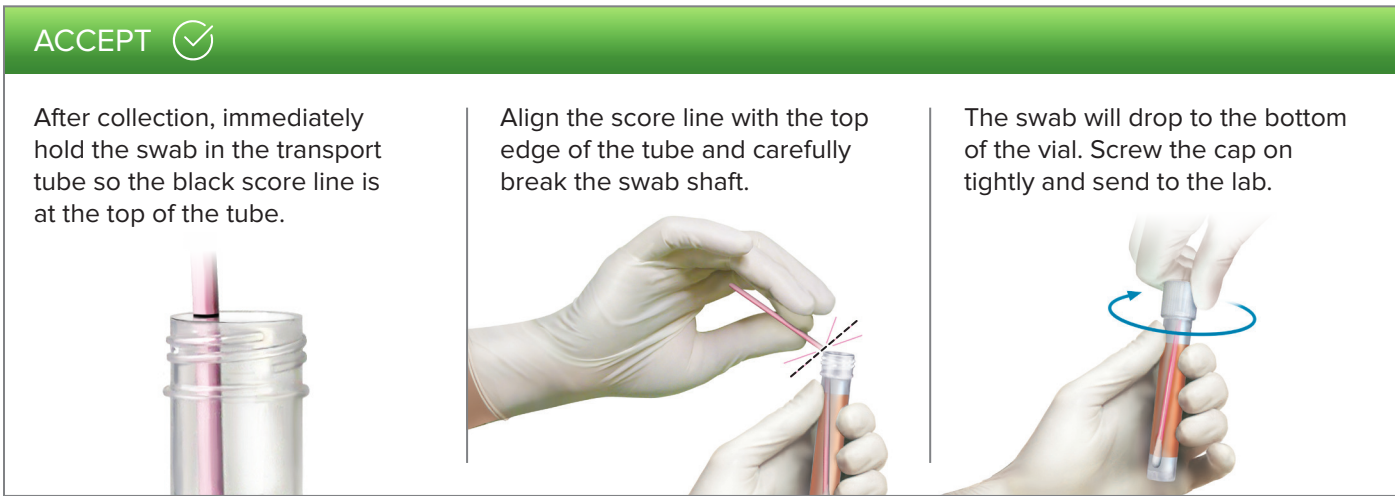
- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (NG)
- *Mycoplasma genitalium* (MG)
- *Trichomonas vaginalis* (TV)
- Bacterial vaginosis (BV)
- Candida vaginitis (CV)
- Herpes simplex virus 1 & 2 (HSV)

ACCEPT ✓

After collection, immediately hold the swab in the transport tube so the black score line is at the top of the tube.

Align the score line with the top edge of the tube and carefully break the swab shaft.

The swab will drop to the bottom of the vial. Screw the cap on tightly and send to the lab.

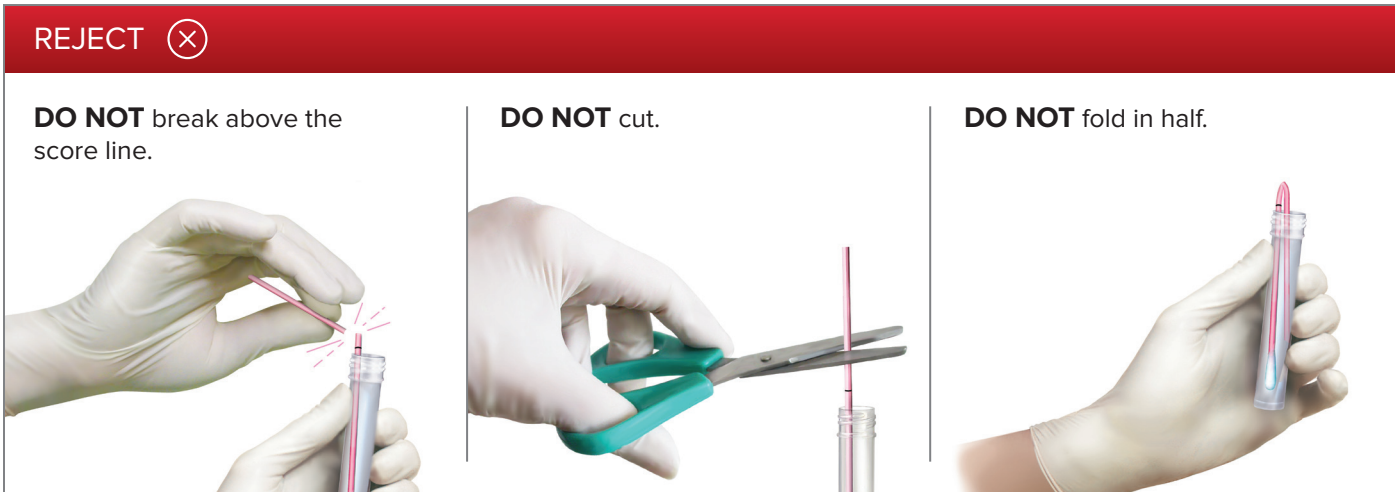


REJECT ✗

DO NOT break above the score line.

DO NOT cut.

DO NOT fold in half.



Visually inspect to confirm the swab is broken at the score line.

Hologic provides this collection procedure guide as a general informational tool only; it is not an affirmative instruction or guarantee of performance. It is the sole responsibility of the laboratory to read and understand the appropriate package insert and comply with applicable local, state and federal rules and regulations.

hologic.com | diagnostic.solutions@hologic.com | +1.888.484.4747

DS-01554-001 Rev. 005 © 2019 Hologic, Inc. All rights reserved. Hologic, The Science of Sure, Aptima and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. This information is intended for medical professionals in the U.S. and other markets and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshows, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, please contact your Hologic representative or write to diagnostic.solutions@hologic.com.

Aptima® Unisex Swab Specimen Collection Kit

Female collection procedure guide

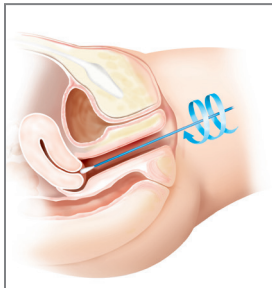
Collection for endocervical swab specimens



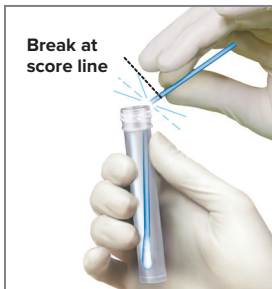
Use cleaning swab (white shaft swab with red printing) to remove excess mucus from cervical os and surrounding mucosa. Discard this swab.

Swab specimen collection guide for:

- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (NG)
- *Mycoplasma genitalium* (MG)
- *Trichomonas vaginalis* (TV)



Insert collection swab (blue shaft swab with green printing) into endocervical canal. Gently rotate swab clockwise for 10 to 30 seconds to help ensure adequate sampling. Withdraw swab carefully; avoid any contact with vaginal mucosa.



While holding swab in hand, unscrew the tube cap. Do not spill tube contents. **If the tube contents are spilled, discard and replace with a new Aptima unisex swab transport tube.** Carefully break the swab shaft at the score line against the side of the tube. Discard top portion of swab shaft.



Re-cap swab specimen transport tube tightly.

Specimen Transport and Storage

- After collection, transport and store swab in the unisex specimen transport tube between 2°C to 30°C until tested for Aptima Combo 2® assay, Aptima® Mycoplasma genitalium assay and Aptima® Trichomonas vaginalis assay.
- Specimens must be assayed within 60 days of collection for Aptima Combo 2® assay, Aptima® Mycoplasma genitalium assay and Aptima® Trichomonas vaginalis assay.
- If longer storage is needed, after collection in the Aptima unisex specimen transport tube freeze between -20°C to -70°C for up to 12 months for Aptima Combo 2® assay, up to 90 days for Aptima® Mycoplasma genitalium assay and up to 24 months for the Aptima® Trichomonas vaginalis assay.



Aptima[®] Unisex Swab Specimen Collection Kit

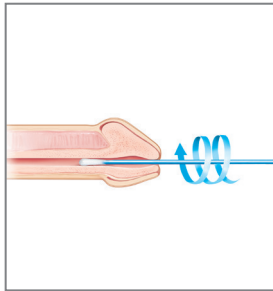
Male collection procedure guide

Collection for male urethral swab specimens

Patient should not have urinated for at least 1 hour prior to specimen collection.

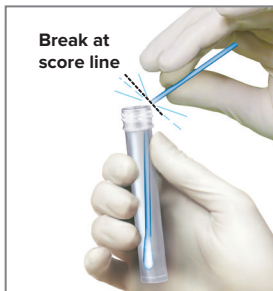
Swab specimen collection guide for:

- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (NG)
- *Mycoplasma genitalium* (MG)



Discard cleaning swab (white shaft with red print on label). The cleaning swab is NOT needed for male specimen collection.

Insert specimen collection swab (blue shaft swab with green printing) 2 cm to 4 cm into urethra. Gently rotate swab clockwise for 2 to 3 seconds in urethra to help ensure adequate sampling. Withdraw swab carefully.



While holding swab in hand, unscrew tube cap. Do not spill tube contents. **If tube contents are spilled, discard and replace with a new Aptima unisex swab transport tube.** Carefully break the swab shaft at the score line against the side of the tube. Discard top portion of swab shaft.



Re-cap swab specimen transport tube tightly.

Specimen Transport and Storage

- After collection, transport and store swab in the unisex specimen transport tube between 2°C to 30°C until tested for Aptima Combo 2[®] assay, Aptima[®] Mycoplasma genitalium assay and Aptima[®] Trichomonas vaginalis assay.
- Specimens must be assayed within 60 days of collection for Aptima Combo 2[®] assay, Aptima[®] Mycoplasma genitalium assay and Aptima[®] Trichomonas vaginalis assay.
- If longer storage is needed, after collection in the Aptima unisex specimen transport tube freeze between -20°C to -70°C for up to 12 months for Aptima Combo 2[®] assay, up to 90 days for Aptima[®] Mycoplasma genitalium assay and up to 24 months for the Aptima[®] Trichomonas vaginalis assay.

Hologic provides this collection procedure guide as a general informational tool only; it is not an affirmative instruction or guarantee of performance. It is the sole responsibility of the clinician/laboratory to read and understand the appropriate package insert and comply with applicable local, state and federal rules and regulations.

hologic.com | diagnostic.solutions@hologic.com | 888.484.4747

DS-01696-001 Rev. 003 © 2019 Hologic, Inc. All rights reserved. Hologic, The Science of Sure, Aptima, Aptima Combo 2 and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. This information is intended for medical professionals in the U.S. and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshows, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, please contact your local Hologic representative or write to diagnostic.solutions@hologic.com.



Aptima® Urine Specimen Collection Procedure

Aptima Combo 2®
Assay for CT/NG

Aptima® Mycoplasma genitalium
Assay

Aptima® Trichomonas vaginalis
Assay

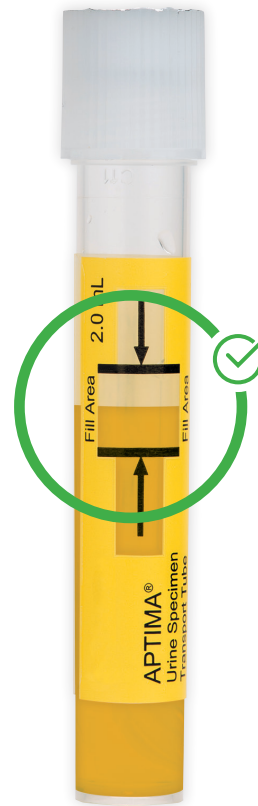
Aptima® Zika Virus
Assay



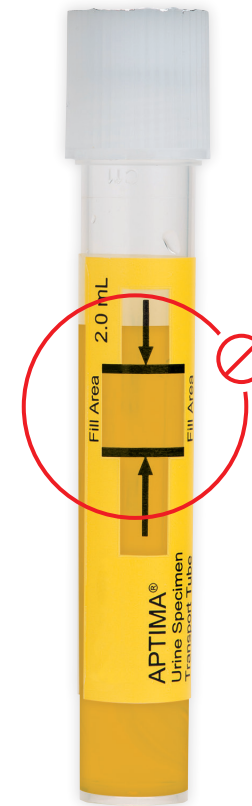
Overfilling or underfilling will require a new sample collection tube to obtain a valid result.

Transfer urine into collection tube.

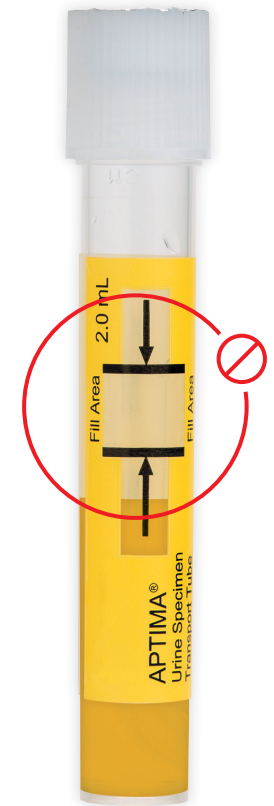
Fill between black lines only.



ACCEPT



**OVERFILLED
REJECT**



**UNDERFILLED
REJECT**

Refer to the geography-specific package insert for specific sample type availability.

* The Aptima Zika Virus assay:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Aptima[®] Urine Collection Kit

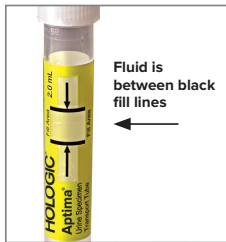
Collection procedure guide

Collection for male and female urine specimens

Patient should not have urinated for at least 1 hour prior to specimen collection.



Direct patient to provide **first-catch** urine (approximately 20 to 30 mL of initial urine stream) into urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity. Female patients should not cleanse labial area prior to providing specimen.



Remove cap from urine specimen transport tube and transfer 2 mL of urine into urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on urine specimen transport tube label.



Re-cap urine specimen transport tube tightly. This is now known as the “processed urine specimen.”

Specimen transport and storage

- Urine samples still in primary collection container must be transported to the lab between 2°C to 30°C. Transfer urine sample into Aptima urine specimen transport tube within 24 hours of collection for Aptima Combo 2[®] assay for CT/NG, Aptima[®] Mycoplasma genitalium assay or Aptima[®] Trichomonas vaginalis assay and within 72 hours for Aptima[®] Zika virus assay.
- Transport and store processed urine specimens in the Aptima urine specimen transport tube between 2°C to 30°C until tested.
- Processed urine specimens should be assayed for Aptima Combo 2[®] assay for CT/NG, Aptima[®] Mycoplasma genitalium assay, Aptima[®] Trichomonas vaginalis assay and Aptima[®] Zika virus assay within 30 days of collection.
- If longer storage is needed, freeze between -20°C to -70°C. Consult package inserts for allowable duration.

The Aptima Zika Virus assay:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Hologic provides this collection procedure guide as a general informational tool only; it is not an affirmative instruction or guarantee of performance. It is the sole responsibility of the clinician/laboratory to read and understand the appropriate package insert and comply with applicable local, state and federal rules and regulations.

hologic.com | diagnostic.solutions@hologic.com | 888.484.4747

DS-01697-001 Rev. 003 © 2019 Hologic, Inc. All rights reserved. Hologic, The Science of Sure, Aptima Combo 2, Aptima and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. This information is intended for medical professionals in the U.S. and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshows, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, please contact your local Hologic representative or write to diagnostic.solutions@hologic.com.

Urine specimen collection guide for:

- *Chlamydia trachomatis* (CT)
- *Neisseria gonorrhoeae* (NG)
- *Mycoplasma genitalium* (MG)
- *Trichomonas vaginalis* (TV) for female only
- *Zika virus* (Zika)
(collect alongside a blood sample)

Confirm with your laboratory if these samples types are acceptable.

