# Updates and Reminders

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# VOICE shipping and close out

- Thanks to the sites for all the efforts to get out shipments quickly to expedite endpoint verification for the DSMB.
- Please let the NL know if any documents are needed to be sent with shipping requests to expedite the process.
- Please carefully review instructions in the shipping emails

# VOICE shipping and close out

- As study closeout begins, there will be pressure on the sites and NL to verify endpoints and perform HIV testing QA
- Once study visits are complete, other specimens such as cervical and vaginal swabs will be shipped.
- Gram stain shipments will be ongoing…

# Sample Destruction Procedure

- Specimens collected from screening participants who did not enroll.
  - New LDMS report
  - Cross check with your site screening and enrollment report
  - Must be done before shipping specimens to the NL

# Sample Destruction Procedure

- Specimens collected from participants who enrolled but did not consent to long term storage
  - Do not destroy these samples until notified by SCHARP and the NL
  - SCHARP will generate a list of PTIDS to be destroyed

# EQA updates

- hCG
  - Switching from CAP to Accutest in 2012
    - Accutest sends 15 samples per year.
    - Some samples have low quantities of hCG
- Syphilis EQA vs. study samples
  - Report both the RPR and TPHA
- Save CAP and Accutest samples
  - Use for retesting if results are incorrect
  - Use for QC, validation, or training

# Supply requests

- Check the inventory of kits and outdates to reduce the number of shipments.
  - BVBlue, OSOM rapid Trich, pH paper, urine dipsticks, controls
- Send your request 1 month in advance to Wayne Hall, Lorna Rabe, and Edward (Ted) Livant
- Include at least one other person from your site on the e-mail request incase the initial person is not available to receive the shipment.
- MTN does not have supplies in stock. We order from the US distributor. Kits are delivered to our lab in 1-2 weeks depending on the item and if they are in stock at the distributor

# Invoices for supplies

- the invoice sent with the package is an estimate of the cost for customs purposes
- A second invoice is sent from the MTN finance department about 1 month later that includes the shipping costs
- Any billing inquires are to be directed to: Nicole Lazor: lazorn@mwri.magee.edu

# How to store Gram stain slides and enter into LDMS

- Use two slide boxes, one for the slides to be shipped and the other for the backup slide
- Entering into LDMS:
  - storage module
  - Configuration
  - Fill order: change to top to bottom, left to right
  - Coordinates: columns, rows
  - # of columns: 1, # of rows: 100

# Shipping slides to Network Lab

- Ship only boxes of 100 slides
- Notify Ted, Wayne, and Lorna when shipping slides
  - Send tracking number
  - LDMS formatted manifest: send by e-mail (not .csv)
- Preparing the slides for shipment
  - Put several paper towels in the lid of the boxes to prevent slides from moving. (shake the box and if it rattles add more paper towels.
  - Wrap tape around the box to secure lid.
  - Use bubble wrap, paper, or Styrofoam packing material
- FedEx, DHL, or World Courier

# BVBlue

- Rapid test that detects elevated levels of sialidase
- Previous published studies showed a sensitivity between 89-100%
- Preliminary results from the VOICE enrollment visits

# Results: BVBlue vs Gram Stain in VOICE Study

| BVBlue test N=371 | Gram stain | |
|---|---|---|
| | Positive (Nugent 7-10) n = 151 | Negative (Nugent 0-6) n = 220 |
| Positive | 78 | 12 |
| Negative | 73 | 208 |

Sensitivity 52%
Specificity 96%

Positive Predictive value 87%
Negative Predictive value 74%

# BVBlue Results by Sites

| Sites | Total tested | BVBlue positive | Gram stain score 7-10 | Sensitivity | Specificity |
|---|---|---|---|---|---|
| All Sites | 371 | 90 (24%) | 151 (41%) | 52% | 96% |
| Verulam | 94 | 23 (24%) | 41 (43%) | 49% | 94% |
| Botha Hills | 67 | 18 (27%) | 35 (52%) | 49% | 97% |
| Umkomaas | 59 | 7 (12%) | 14 (24%) | 50% | 100% |
| RK Khan | 53 | 11 (21%) | 22 (42%) | 50% | 97% |
| Tongaat | 33 | 14 (42%) | 13 (39%) | 69% | 75% |
| Overport | 18 | 3 (17%) | 9 (50%) | 33% | 100% |
| Isipingo/eThikwini | 8 | 2 (25%) | 3 (38%) | 67% | 100% |
| Aurum/WRHI | 27 | 7 (26%) | 10 (37%) | 60% | 94% |
| Zimbabwe | 8 | 1 (13%) | 2 (25%) | 50% | 100% |
| Uganda | 4 | 3 (75%) | 2 (50%) | 100% | 50% |

# Women with Gram Stain Positive for BV (Score 7-10)

| | BVBlue pos | BVBlue neg | P value |
|---|---|---|---|
| N | 78 | 73 | |
| Mean Gram stain score | 8.7 | 8.3 | 0.03 [1] |
| Yeast present on GS | 4 (5%) | 4 (5%) | NS |

| | WBC [2] | | | | |
|---|---|---|---|---|---|
| | 0 | 1+ | 2+ | 3+ | |
| **BVBlue pos** | 51 | 17 | 10 | 0 | P value=0.009 [3] |
| **BVBlue neg** | 37 | 18 | 9 | 9 | |

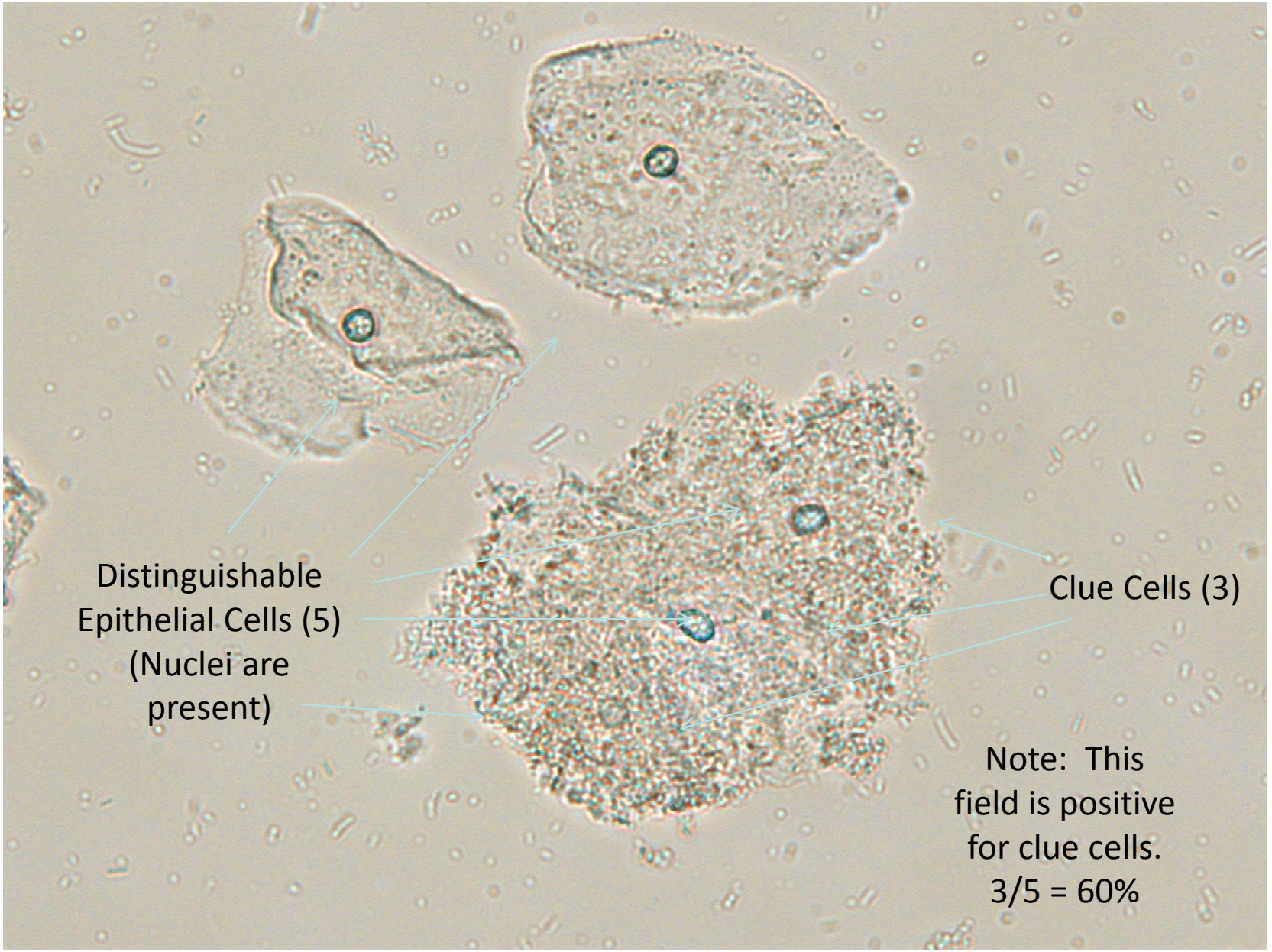
1. Mann Whitney
2. <1 WBC/1000X=1+, 1-4 WBC/1000X=2+, 5-30 WBC/1000X=3+
3. Chi Square for linear trend

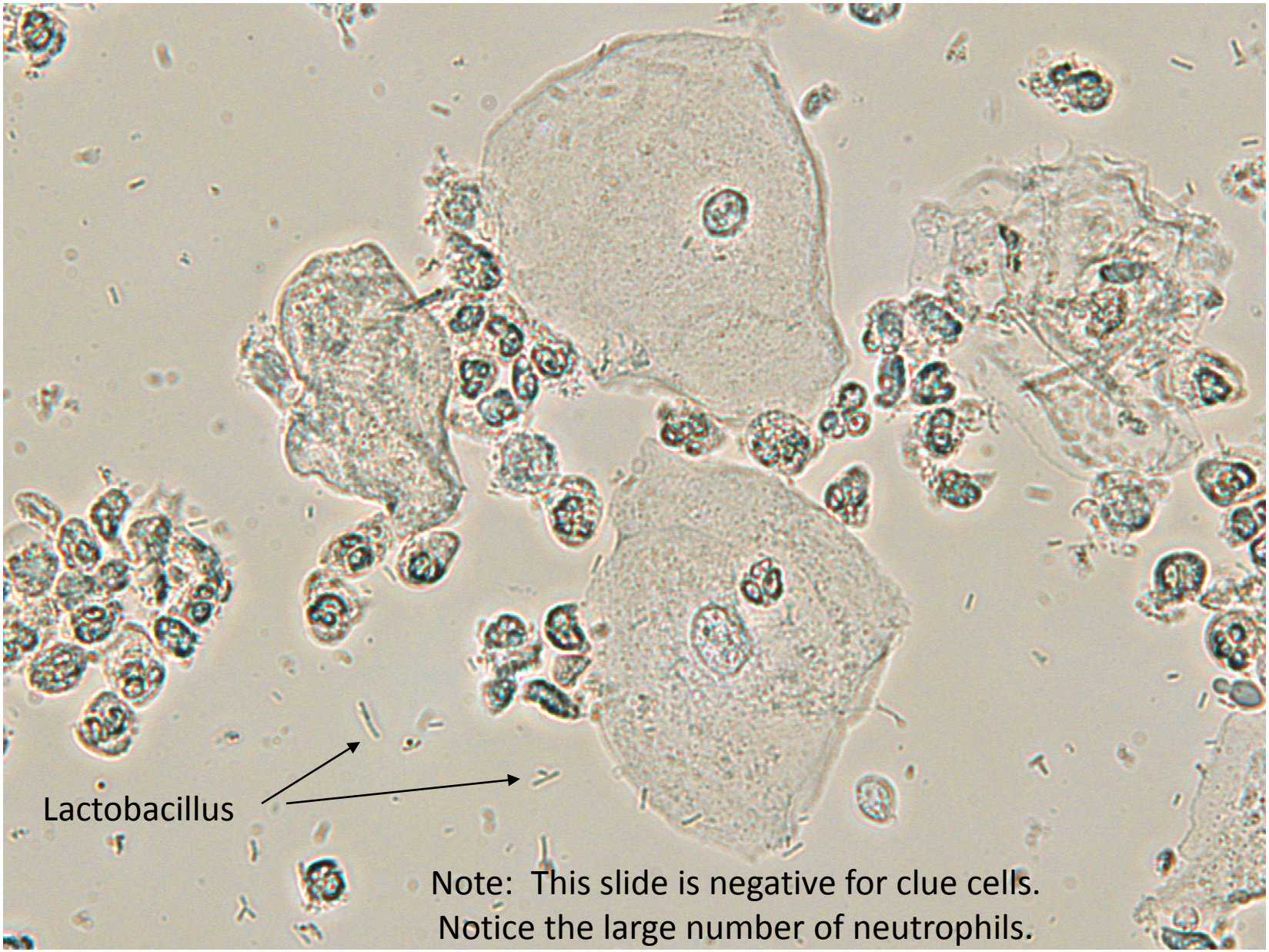
# Diagnosis of BV

- BVBlue will continue in VOICE
- BVBlue will NOT be used in MTN 020 (ASPIRE) study
- Amsel criteria will be use for MTN 020

# Wet mount proficiency test

- Send list of readers and their email addresses to Michele Austin and Lorna Rabe
- Please stress to the readers that they need to take the tests as soon as possible.
  - If they fail the initial test they will need to take another test before the deadline date
- A set of training slides are available at the MTN website located in the network/laboratory/wet mount proficiency
  - Use this as a refresher or to supplement your training


Distinguishable Epithelial Cells (5) (Nuclei are present)
Clue Cells (3)
Note: This field is positive for clue cells. 3/5 = 60%


Lactobacillus
Note: This slide is negative for clue cells.
Notice the large number of neutrophils.

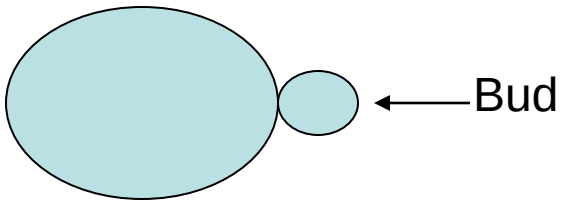
# Reading KOH Wet Preps

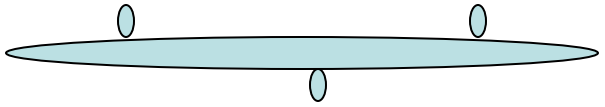
- The following tips can be utilized in order to correctly identify pseudohyphae and yeast in a wet prep.

  1. Pseudohyphae must have yeast “budding off” of the tubular structure in order for it to be correctly identified as pseudohyphae. If there are no “buds” present, it is not pseudohyphae.

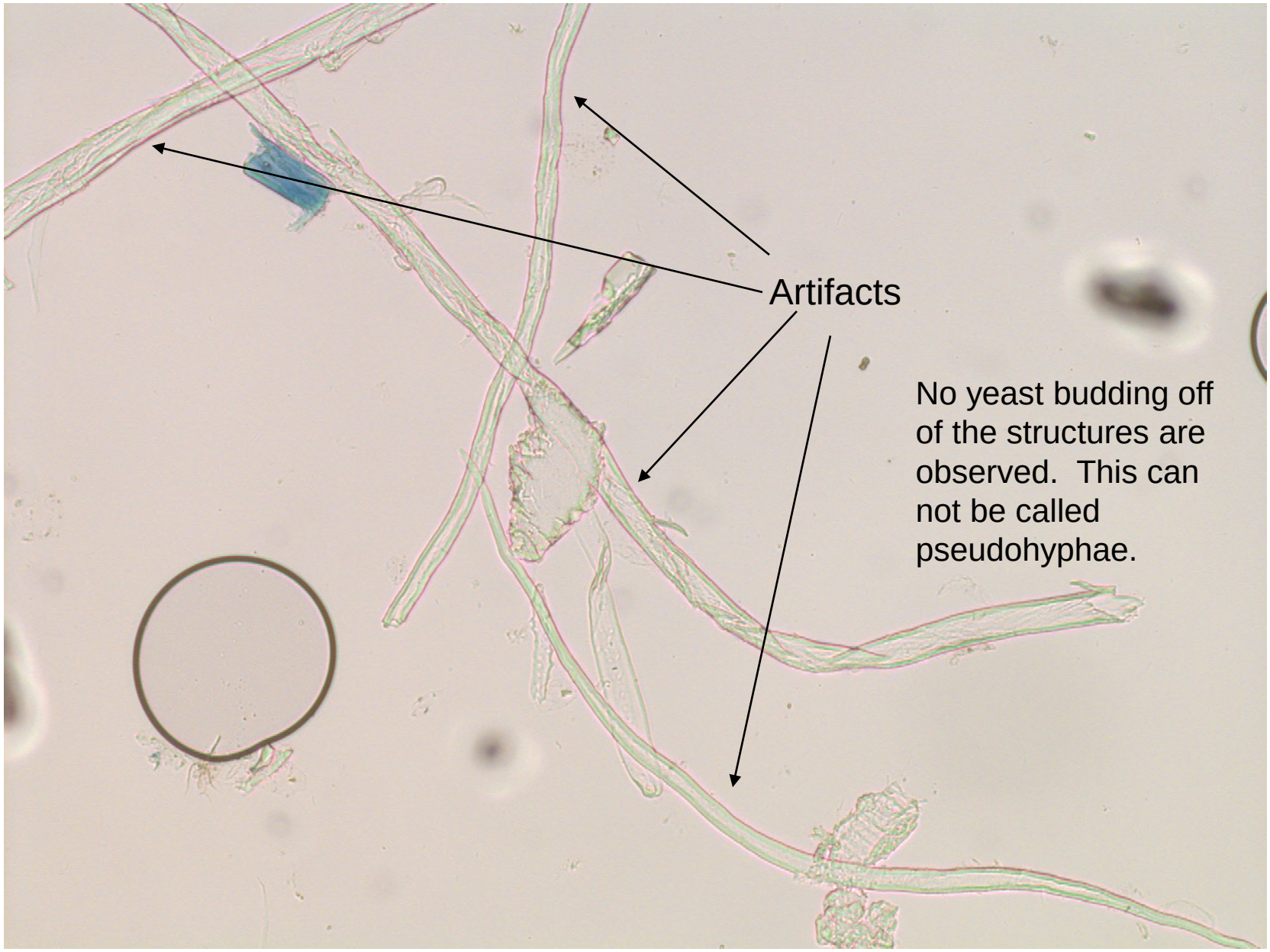
  2. In order for yeast not to be mistaken for nuclei of cells, they must be “budding”. This form resembles a larger oval with a smaller oval attached at one end. Without the bud, the yeast would look like a nuclei.

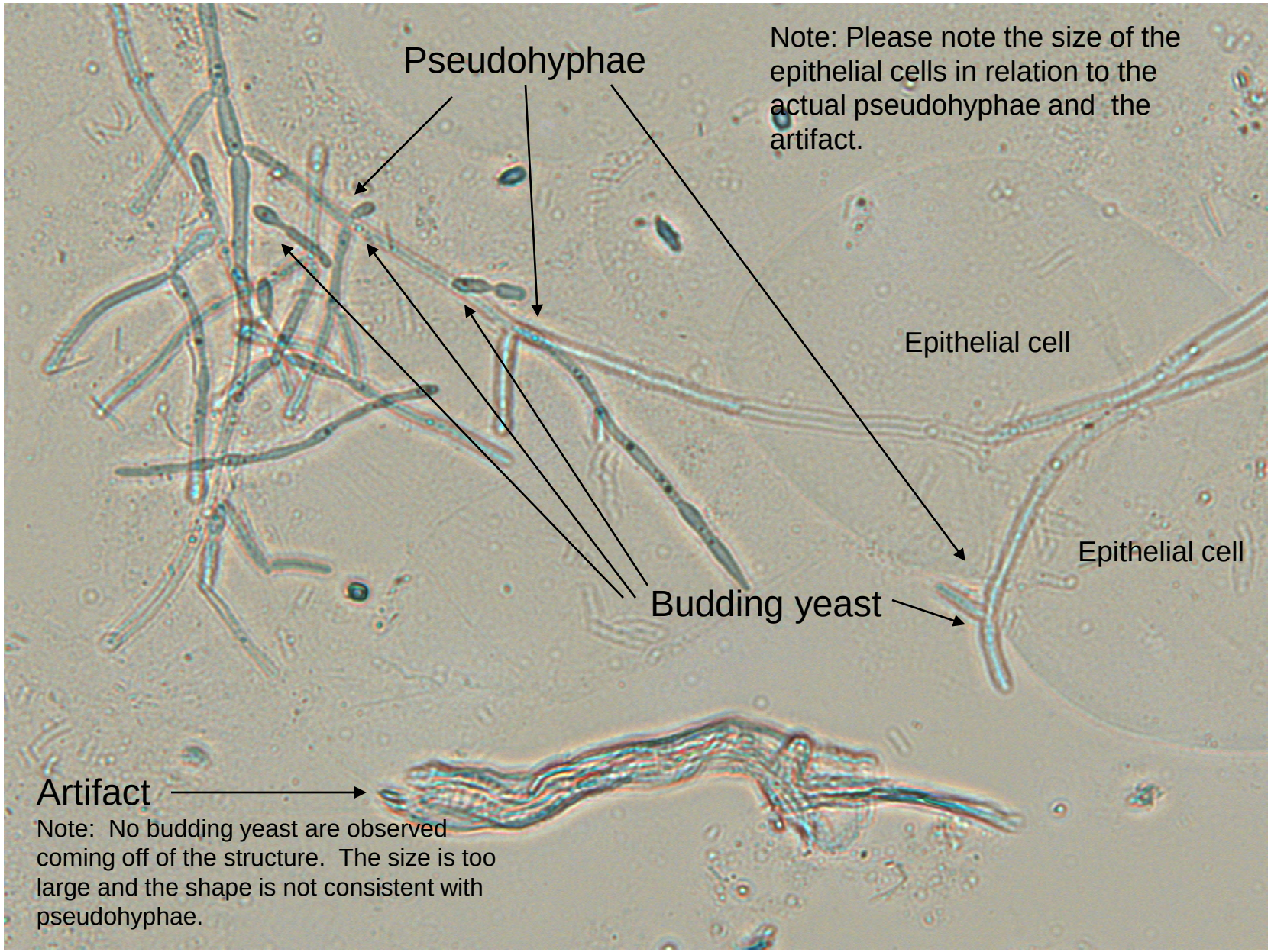
Example:



Pseudohyphae with “buds”


Artifacts
No yeast budding off of the structures are observed. This can not be called pseudohyphae.


Pseudohyphae
Note: Please note the size of the epithelial cells in relation to the actual pseudohyphae and the artifact.
Epithelial cell
Epithelial cell
Budding yeast
Artifact
Note: No budding yeast are observed coming off of the structure. The size is too large and the shape is not consistent with pseudohyphae.