

Doctor tests

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Doctor test



Are DTs used

2 examples

- Urine dipstick test : 1980s
- Strep A tests : 1990s

Urine dipstick test for UTI

Based on :

- **Sensitivity :**
 - Nitrites 50-70 %
 - Leucocyte esterase 60-80 %
 - Any of the two 75 - 85 %
- **Specificity :**
 - Single marker 75 – 85 %
 - Any of the two : ~ 60 %
- **Prevalence of UTI : ~ 20 %**
(can increase with more stringent case definition)

PPV ~ 40 % (i.e. higher than PPV of clinical scoring),

NPV ~ 95 %

~ 4 missed UTIs in 100 tested patients

**Could allow to spare a substantial
proportion (half) of useless treatments**

Urine dipstick test : recommendations for UTIs in textbooks

Mandell 2005

- “rapid screening test.... Patients with a negative test and UTI symptoms should have urine microscopic examination or culture”

Manual of clinical microbiology (8th edition)

- rapid, inexpensive and simple to perform..... Sensitivity is low in some patient populations..... Screening algorithms have been proposed that incorporate test (positive = culture, negative = no culture)

Urine dipstick test

And in practice ? (1)

- Nys JAC 2006
- 21 GPs, the Netherlands
- Guidelines :
 - Ni + = positive test > treatment
 - Ni - and Le - = negative test > no treatment
- 1993 non pregnant women, mean age 43 years
- women with Ni + : 94 % got antibiotics (recommend.)
- women **with Ni- and Le - : 20 % got antibiotics**

Urine dipstick test

And in practice ? (2)

- Patel J Clin Patol 2006
- 3 hospitals, 1 central lab, Leicester UK
- Dipstick + strip reader (automated, paper printouts)
- Prevalence UTI 17 %
- Policy : negative test >> no urine sent for culture
- Impact of policy assessed after 2 years
- Reduction in Lab workload (i.e. in number of urine samples sent for culture)
- **Hospital 1 : - 6 %**
- **Hospital 2 : - 19 %**
- **Hospital 3 : + 44 %**
- **no clear reason for discrepancies within hospitals**

Urine dipstick test

And in practice ? (3)

- In many places performed **in the Lab** as screening test
- To reduce Lab workload : e.g. if 4 criteria are used (Ni, Le, blood, protein), samples with all 4 negative (15 - 20%) can be ruled out
- now in competition with automated rapid screening methods

Strep A tests

- rapid immuno-chromatographic assay
- qualitative detection of StrepA antigen directly from throat swab
- various formats : dipstick, cards, cartridges..



ICON® DS Strep A



ICON® SC Strep A



Strep A tests

Based on :

- Global **sensitivity** 85-90% and **specificity** 95-98%
- **Prevalence** of strepA in children with pharyngitis :
20 to 40 % (can vary depending on clinical score, e.g. Centor score), mean 30 %

PPV ~ 90 %, i.e. >>> PPV of clinical score

NPV ~ 95 %

~ 3 missed StrepA cases in 100 tested children

**Could allow to spare a substantial
proportion (3/4) of useless treatments**

Strep A tests : recommendations for pharyngitis in children

Some say :

- Positive test can be used to start treatment (~ 20%)
- Negative test should be confirmed by culture !!!
- Providing highest diagnosis rate and lowest level of unnecessary antibiotic prescription

Others say :

- Positive test can be used to start treatment (~ 20%)
- Negative test can be used not to treat, without confirmation by culture

Strep A tests : recommendations for pharyngitis in children

Other criteria

- Sensitivity of the test can vary depending on practitioner
- Financial cost : lowest seems to be “treat all” policy (studies generally take penicillin cost in models, but not the more expensive antibiotics)
- Societal cost and care strategy : “my child has no StrepA and goes back to school tomorrow ...”

Strep A tests : recommendations for pharyngitis in children

And in practice ?

- Atlas J Gen Intern med 2005
- Primary care setting, Mass. Gen Hosp Boston
- **StrepA rapid test used as Point of care**
- 179 patients with pharyngitis
- Prevalence StrepA 26 %
- All patients with positive test got treated
- 1/4 patients with negative test got treated
- Crude antibiotic treatment “saved” over the “treat all” policy : 55 %

Doctor tests limitations

Why doctors could be reluctant to use DTs

- Take time, even not much
- Accessibility (how to get the kits)
- Not that easy to perform
- “I’m not a biologist”
- Perception of the economic issue (cost saving), societal issue (e.g. back to home), ecological issue (decrease antibiotic use)
- Underpaid test
- Willing to share the responsibility for the diagnosis (legal concern...)

Doctor tests limitations : consequences

- Not performed at all
- Performed by doctors but with a limited impact on decision
- Performed in the Lab (« they know how to do it and have the time to do it »)

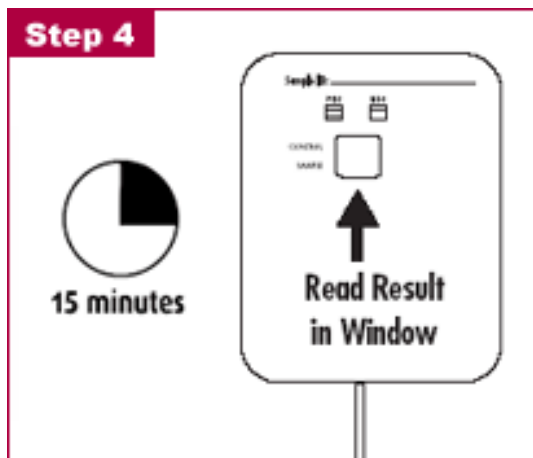
BINAX NOW® Legionella



BinaxNOW
Legionella
Features and Benefits



- Urinary Antigen
- «most widely recognized rapid urine tests in the world due to its sensitivity, specificity and ease of use »



- «sensitivity 95%, specificity 95%»
- results in 15 minutes
- **Moderately Complex**

Influenza A+B

- X/pect Flu A & B
- Result in 15 minutes
- directly from nose or throat swabs.
- « extremely easy to perform and interpret, **giving virologists quick and valuable information with which to target further investigations and patient care** ».
- « **improves laboratory workflow** during what can be a hectic season with a high demand for rapid respiratory disease testing »



Respiratory syncytial virus

- dipstick immunoassay
- qualitative detection
- directly from nasopharyngeal swab or nasopharyngeal aspirate
- symptomatic patients ≤ 18 years
- « It is **recommended** that **negative test be confirmed by cell culture** »
- « Negative results do not preclude RSV infection and it is **recommended that they not be used as the sole basis for treatment or management decisions.**

Results in
15 minutes
QuickVue® RSV



Doctor tests in Google

(key word : « doctor test »)

Pregnancy test

- a digital display spells out « Pregnant » or « Not Pregnant », eliminating the need to interpret result lines.
- a blinking display indicates the test is being performed properly and the woman has sampled correctly.
- result in less than 3 minutes.
- £13.99



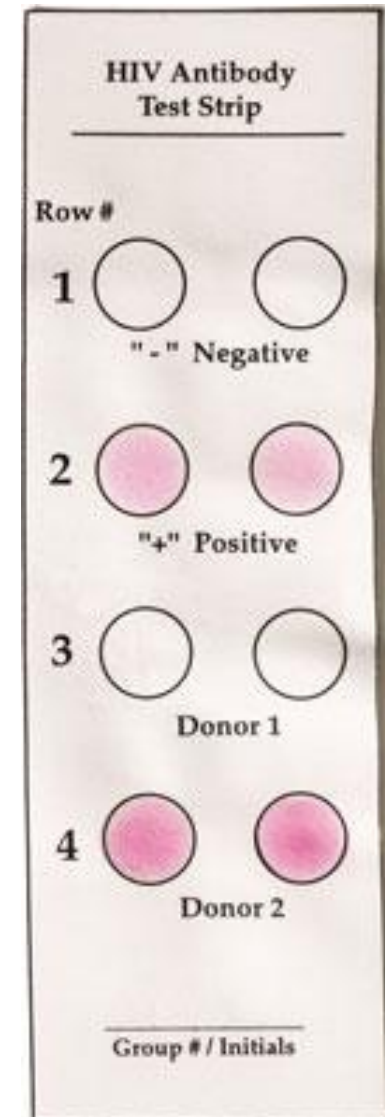
A fake « Doctor Test for AIDS » for training students

Simulated ELISA test to identify
« infected patient samples » and compare
them to control samples.

No human blood is used in this
experiment.

The kit includes : complete instructions,
HIV antigens, neg and pos
control, « donor serums »....

For 10 Groups of students Price: \$99.95



Pretend & Play® Doctor Set (for ages 3-6 years)

Price: \$ 14.50



Expanding the scope of Doctor tests

« Test if you get depressed »

- Depression = dysfunction of serotonin and noradrenaline
- Goes with decreased perception of sweet or salt taste
- Strip with low load of salt and sugar to test perception
- Developed at Bristol University UK

Melichar and Donaldson Sciences 29 August 2008

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"Everything came back negative."

Doctor tests

- = Bedside test, Near patient test (NPT)
- Performed by the doctor (nurse) at clinic or bedside >> easy to use, quick
- Result available within minutes (“less time than it would take a sprinter to reach the lab”)
- Addressing important issues in term of patient management

Doctor tests : ideal indications

- When different possible diagnosis each with distinct medical decision
- test able to distinguish between these diagnosis, or at least to establish or eliminate some (one) of them
- High sensitivity to lead to high NPV
- Not much problem with specificity (and then PPV) as long as higher than alternative diagnostic approach (i.e. clinical...)

Point of care test (POCT)

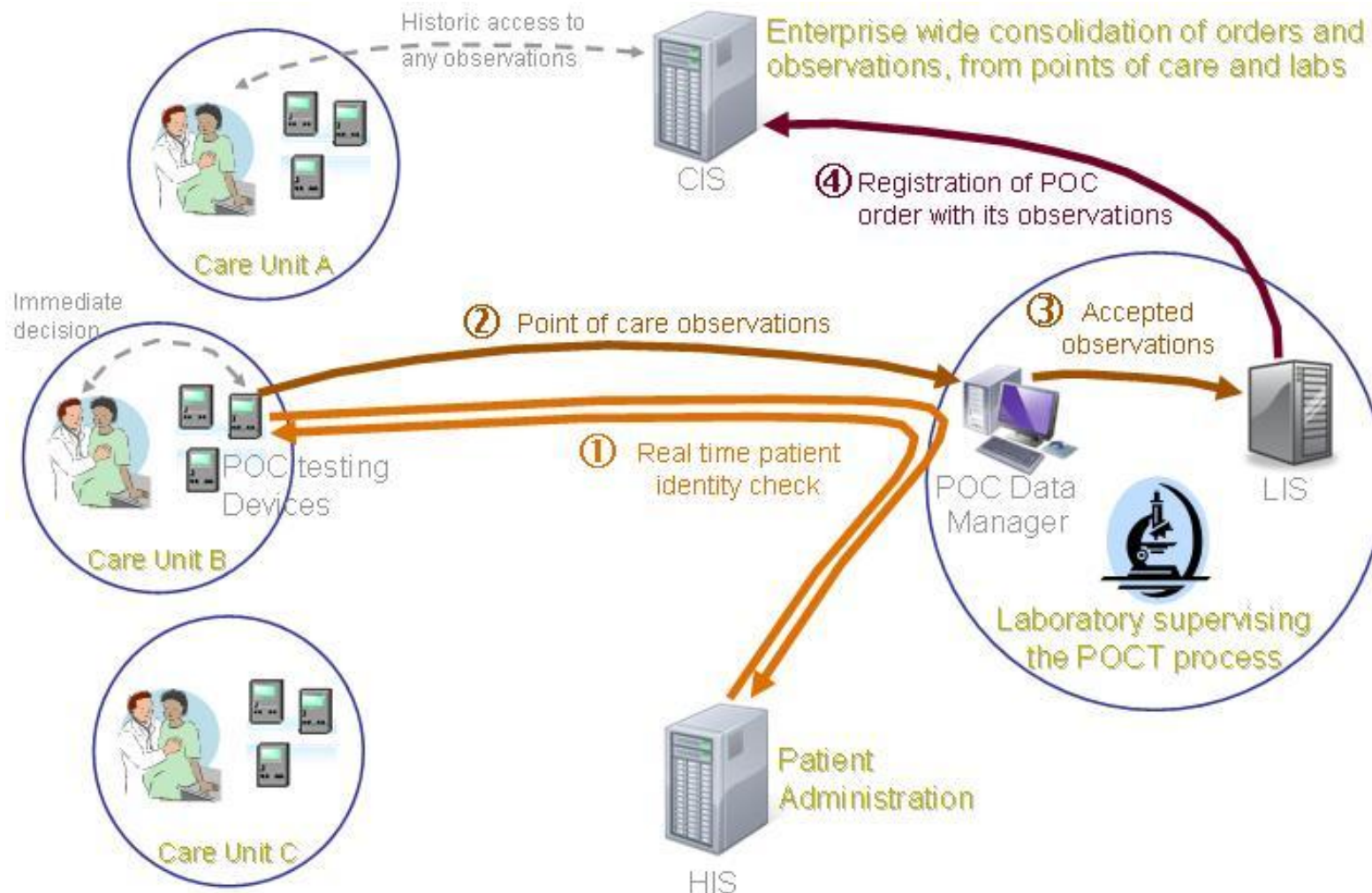
- referred to as near patient, bedside, or extra laboratory testing,
- **key objective of POCT is to generate a result quickly so that appropriate decision can be taken**, leading to an improved clinical or economic outcome
- over the past few years analytical systems have been developed that enable a wide range of tests to be done quickly and simply without the need for sophisticated laboratory equipment.

Point of care tests (POCT) in Google



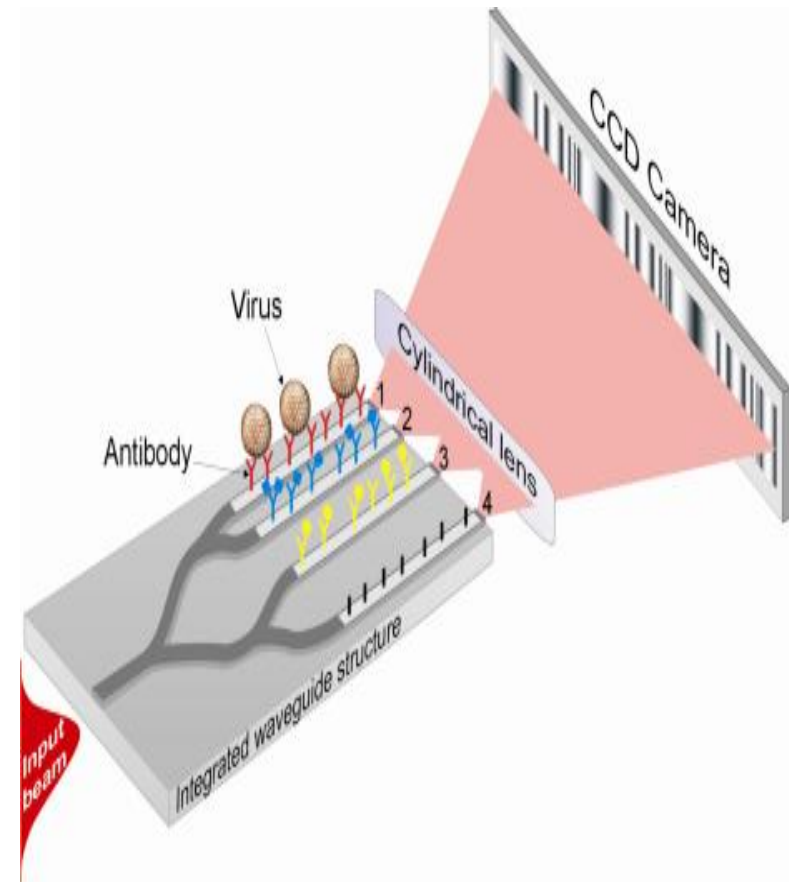
POCTs in Google

« POCTs cover diagnostic tests at the point of care in a healthcare institution »



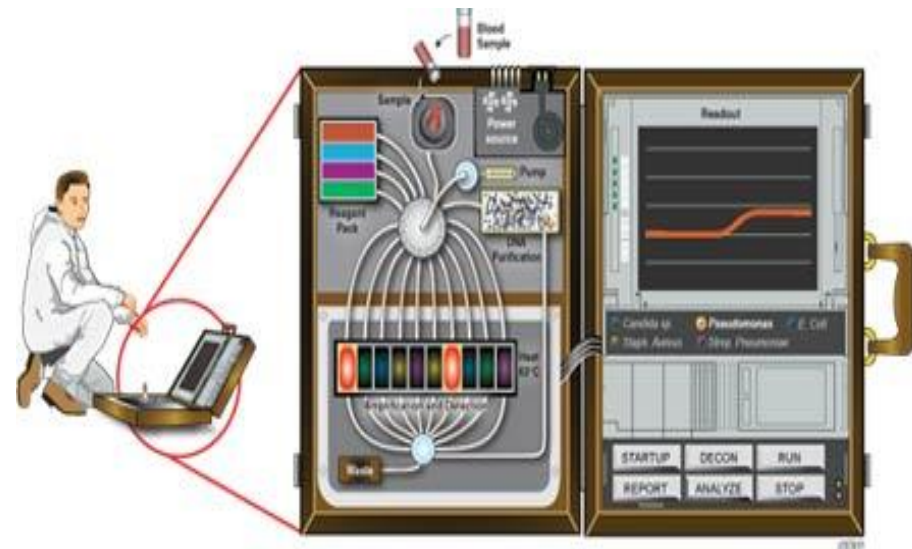
POCTs « for the future » in Google

- “Fast, Sensitive Virus Detector : a sensor measures the concentration of viruses in minutes »
- « Combine integrated optics interferometric sensor and antibody-antigen recognition »
- « Could be used to quickly screen people at airports, hospitals, and emergency clinics to control outbreaks (SARS, bird flu.
- « Rely on a tiny sample of saliva, blood, or other body fluids »



POCTs « for the future » in Google

- Detection of bloodstream infections within 1 hour
- Capability to work at an emergency shelter or at the scene of a disaster
- Expected to result from a five-year, \$8.5 million grant by NIH
- UC Davis Health System and Lawrence Livermore National Laboratory (Ca)



Good
medical microbiology
=
adequate technologies
+
organisation

Microbiologist (lab) close to the
patient !

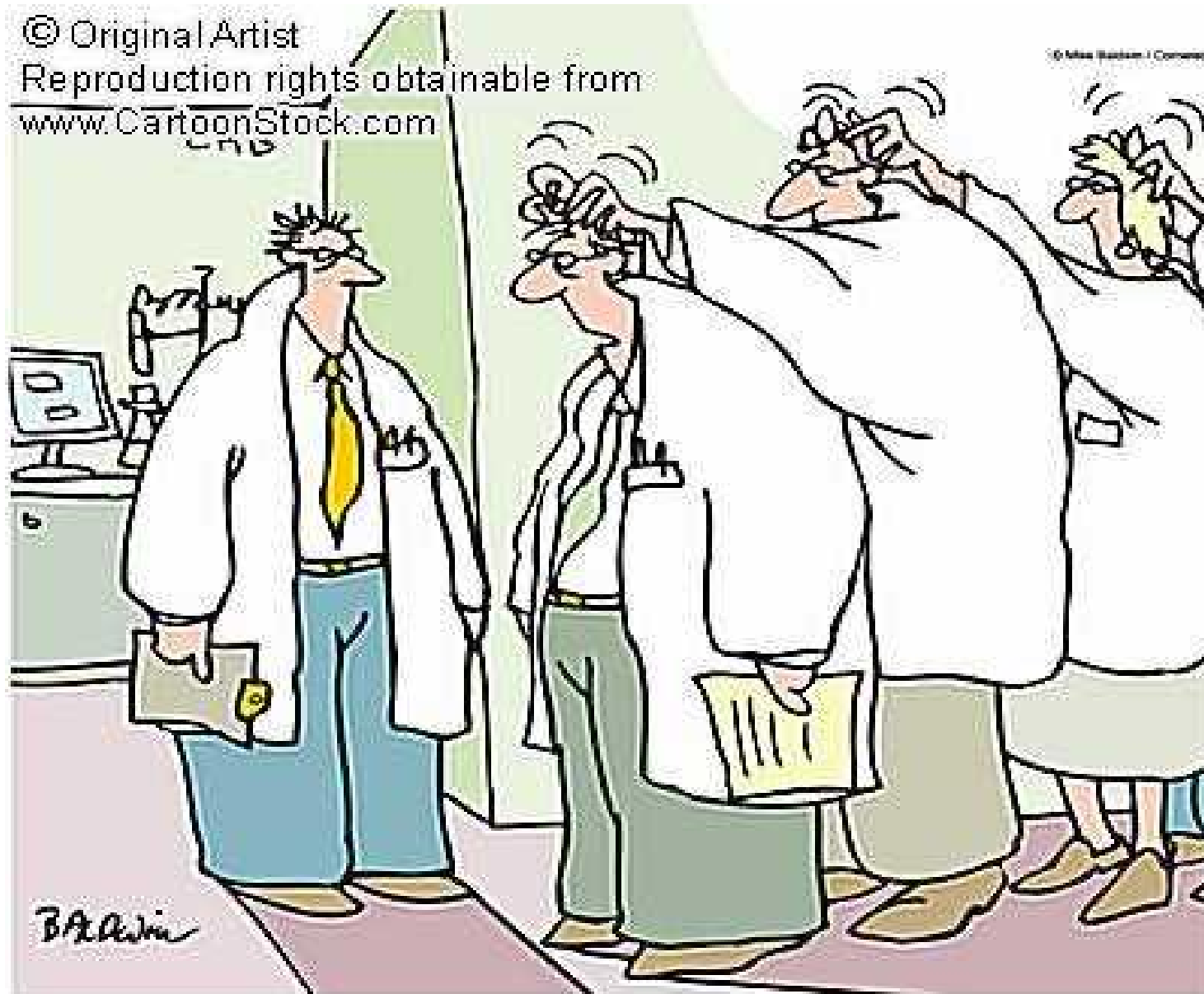
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*"After extensive X-rays and blood tests,
we've confirmed what we already
suspected-- you're not big-boned,
you're fat."*

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"We were just as surprised by the test results as you. We're still scratching our heads over it."

Streptococcus pneumoniae

- urine-based test
- Result in 15 minutes
- for use by healthcare professionals only in hospitals, clinics, **laboratories** and other point-of care settings
- results in 15 minutes
- Classified as **Moderately Complex**



Vaginosis

- enzyme activity test
- detection of *Gardnerella vaginalis* Proline IminoPeptidase(PIP) activity
- vaginal fluid
- Result in 5 minutes
- FDA Cleared
- CLIA Classified as Moderately Complex



Quidel Quikvue Vaginalis Test
25 Tests \$299.95

Influenza A+B

- Immunoassay
- A or B results in 1 test.
- Two-color Result.
- 3 Step Procedure
- 10 Minutes to Result
- Nasal swab, nasal aspirate/wash
- **Sensitivity**
 - A-94%, B 74% - Nasal Swab
 - A-83%, B 67% - Nasopharyngeal swab
 - A-77%, B 82% - Nasal aspirate/wash
- **Specificity**
 - A-90%, B 97% - Nasal Swab
 - A-89%, B 98% - Nasopharyngeal swab
 - A-99%, B 99% - Nasal aspirate/wash
- **QuickVue Influenza A+B**



Doctor tests limitations

- overall efficiency depends very much on human procedures and organization
- If doctors (GPs, emergency room practitioners...) are not trained, or reluctant to use them, DTs are not performed, or performed in the lab !!!

What are claimed by Strep A tests

Technical points

- « **one-step test** »
- « **Single reagent** method: less chance of operator error »
- « **Two color results**: easy to read, eliminate mistakes »
- « **room temperature storage**: saves refrigeration space, no need to warm reagents »

Medical points

- « **In as little as 5 minutes, you will have accurate results** so you can begin your patient's treatment immediately and confidently »
- « **leaves little chance for misdiagnosis**, minimizing the chance of rheumatic fever or over-prescription of antibiotics »
- « take place at the **point of care** »

Pregnancy test

- kit contains 2 tests
- may be used as early as the 1st day of a missed period
- very simple and easy to use
- results in a couple of minutes
- **£10.95**

