



BUSINESS CASE FOR MOLECULAR DIAGNOSTICS TESTING

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CLINICAL SIDE OF BUSINESS CASE

- REPLACING EXISTING TEST?
 - CHLAMYDIA AND GC
 - MSRA
 - VIRAL CULTURES
- NEW TEST?

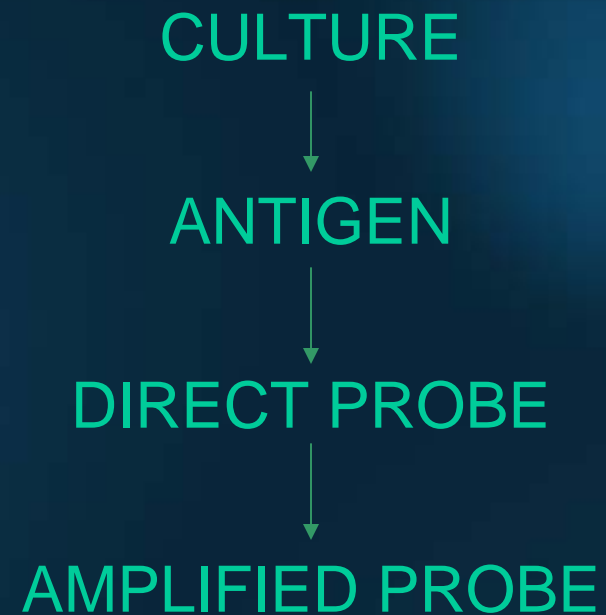


REPLACING EXISTING TEST

- SENSITIVITY
- SPECIFICITY
- POSITIVE PREDICTIVE VALUE
- NEGATIVE PREDICTIVE VALUE

REPLACING EXISTING TEST

EXAMPLE: CHYLAMDIA TESTING





NEWLY DEVELOPED TESTS

- CYSTIC FIBROSIS
- HIV VIRAL LOAD
- FACTOR V LEIDEN
- MRSA



BUSINESS CASE

- COST
 - INSTRUMENTATION
 - LABOR
 - NON-LABOR
- CLINICAL/BUSINESS DEMAND
- IN-HOUSE TEST OR OUTSOURCE
- KIT OR HOME-BREW
- REIMBURSEMENT



BUSINESS CASE - COST

- INSTRUMENTATION
 - EXISTING EQUIPMENT OR NEW EQUIPMENT
 - IF NEW EQUIPMENT: COST
 - PURCHASE
 - LEASE
 - IF NEW EQUIPMENT: USE FOR OTHER FUTURE TESTS



BUSINESS CASE - COST

- LABOR EXPENSE
 - EXISTING STAFF OR NEW STAFF
 - LABOR COST PER PATIENT REPORTABLE TEST
- NON-LABOR EXPENSE
 - REAGENTS AND DISPOSABLES
 - NON-CAPITAL EQUIPMENT
 - OTHER (ROYALTIES, EQUIPMENT MAINTENANCE EXPENSE)



BUSINESS CASE – CLINICAL/BUSINESS DEMAND

- CLINICAL DEMAND
 - VOLUME: PATIENT TESTS PER MONTH
 - SUPPORT OF UPMC CLINICAL SERVICES
 - HOSPITALIZED PATIENTS
 - OUTPATIENT CLINICS
- BUSINESS DEMAND
 - OUTPATIENT TESTING VOLUMES
 - REFERENCE WORK FROM OTHER AREA HOSPITALS AND CLINICS



BUSINESS CASE – URMIC LABS VS OUTSOURCE

- PERFORM IN-HOUSE VERSUS OUTSOURCE
 - DEMAND
 - TESTING VOLUME
 - TURN-AROUND-TIME REQUIREMENTS
 - COST
 - URMIC LABS COST
 - REFERENCE LAB PRICE
 - DIFFICULTY OF WORKUP TO INSOURCE



BUSINESS CASE – KIT VERSUS HOMEBREW

- IS THERE A COMMERCIAL KIT AVAILABLE FOR THIS TEST?
- DOES IT NEED TO BE A “HOMEBREW” TEST
 - FDA
 - NYSDOH



BUSINESS CASE – REIMBURSEMENT

- BILLING (CPT) CODES
 - TEST SPECIFIC CODES
 - 87491 CHLAMYDIA AMPLIFIED PROBE
 - 87536 HIV VIRAL LOAD
 - GENERIC MOLECULAR CODES (EXAMPLES)
 - 83890 MOLECULAR ISOLATION OR EXTRACTION
 - 83894 ELECTROPHORESIS SEPARATION
 - 83896 NUCLEIC ACID PROBE, EACH
 - 83898 AMPLIFICATION
 - 83912 INTERPRETATION AND REPORT



MOLECULAR DIAGNOSTIC TESTING: BUSINESS CASE SUMMARY

- CLINICAL NEED AND VALUE OF THE TEST
- SHOULD IT BE PERFORMED IN OUR LAB OR SENT TO AN EXTERNAL REFERENCE LAB?
- FOR HOSPITALIZED PATIENTS
 - CLINICAL VALUE
 - COST OF TEST



MOLECULAR DIAGNOSTIC TESTING: BUSINESS CASE SUMMARY

OUTPATIENT TESTS

- CLINICAL NEED
- COST VERSUS REIMBURSEMENT
- BILLING
 - SPECIFIC CODE VERSUS GENERIC METHOD CODES
 - MEDICAL NECESSITY CHECKING (REIMBURSEABLE)