

## Topic 001 - UltraSensitive PSA Testing – One Example

UltraSensitive PSA assays (blood tests) are capable of both **higher resolution** and **lower thresholds of detection** than standard PSA “screening tests.” Although multiple laboratories have offered UltraSensitive PSA “monitoring tests” for years, both Prostate Cancer (PC) specialists and policy makers at major medical centers do not **universally** embrace UltraSensitive PSA testing for post treatment monitoring of PC patients following their initial surgery and/or radiation.

Significant confusion today is found among PC patients resulting from this ongoing dispute within the PC industry.

PC physicians and patients do not always speak the same language. There is no better example than discussions regarding the UltraSensitive PSA test. Physicians frequently are quoted as saying “**there is NO clinical significance in the use of the UltraSensitive PSA test.**” It is important for patients to realize that this physician-assertion actually translates as “**at our institution, we would not make treatment decisions differently based on results of PSA UltraSensitive testing.**”

Some physicians falsely imply to patients that the UltraSensitive test is somehow “*not a valid assay.*” Some go so far as to assert that “*there is no science supporting the use of UltraSensitive PSA Testing.*” Such assertions are purely uninformed.

This dispute is not really over the validity of UltraSensitive PSA testing, but instead, this is a dispute among physicians over which disease model should be used for prostate cancer. Physicians who do not support the use of UltraSensitive PSA testing, by definition, simply do not themselves believe that recurrent prostate cancer CAN be forced into remission **IF** treated **APPROPRIATELY AND** treated **EARLY ENOUGH.** **These physicians are actually saying that “this test is not important because early detection of residual disease is not important because early treatment is not important.”**

Several notable PC Oncologists believe that prostate cancer does follow normal “cancer rules” and that UltraSensitive PSA testing **is critical** to early detection which increases their success in obtaining durable remissions through “**early treatment.**”

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[Topic 001.11 - UltraSensitive PSA Testing – Protocol Performance vs. PSA Estimate w/o Intervention @ Two Years](#)

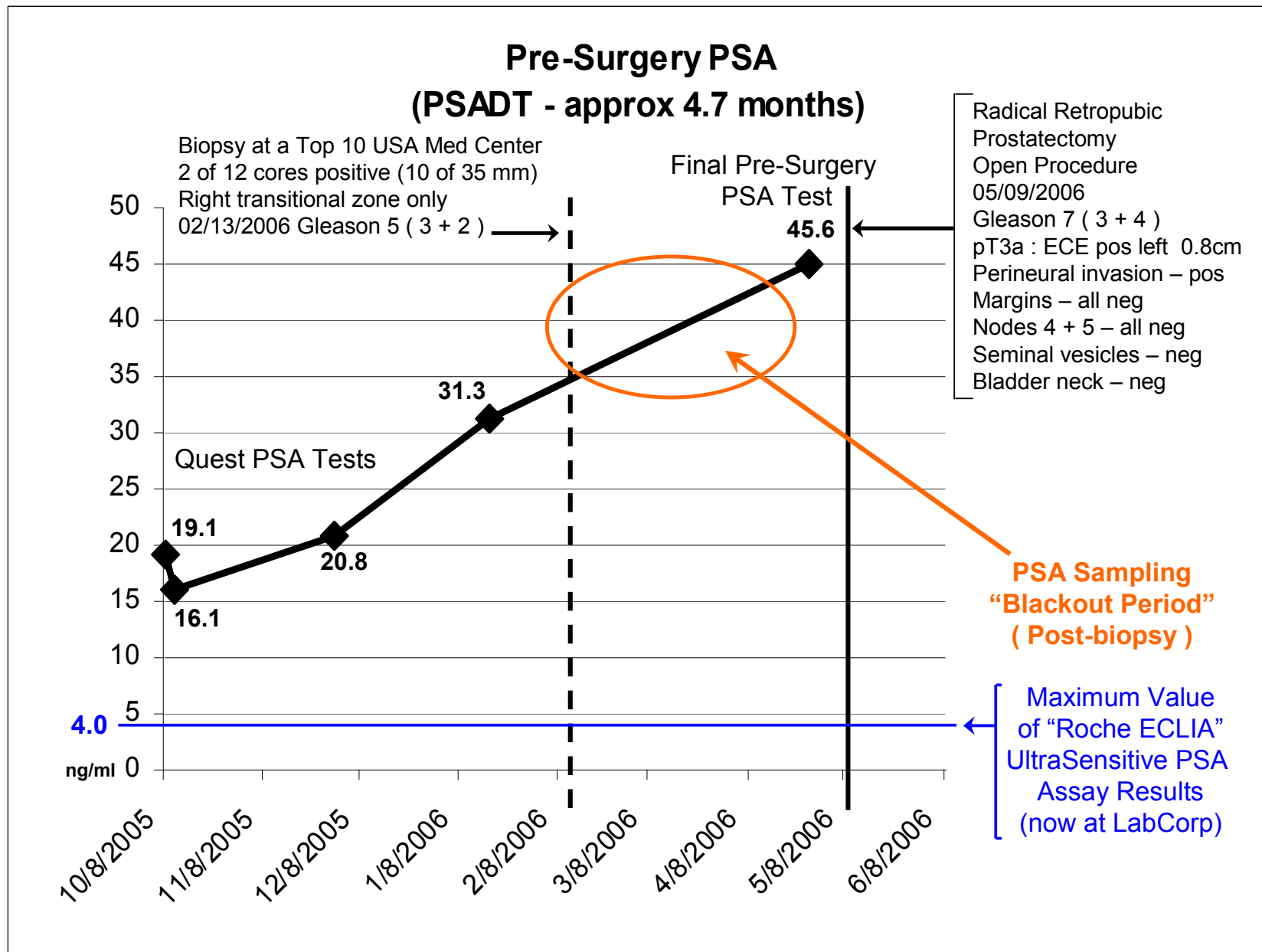
[Reference: Clinical Significance of UltraSensitive PSA Test Results in Post Operative Monitoring](#)

[Reference: Using UltraSensitive PSA Testing To Potentially Gain Years of Earlier Warning of Recurrence](#)

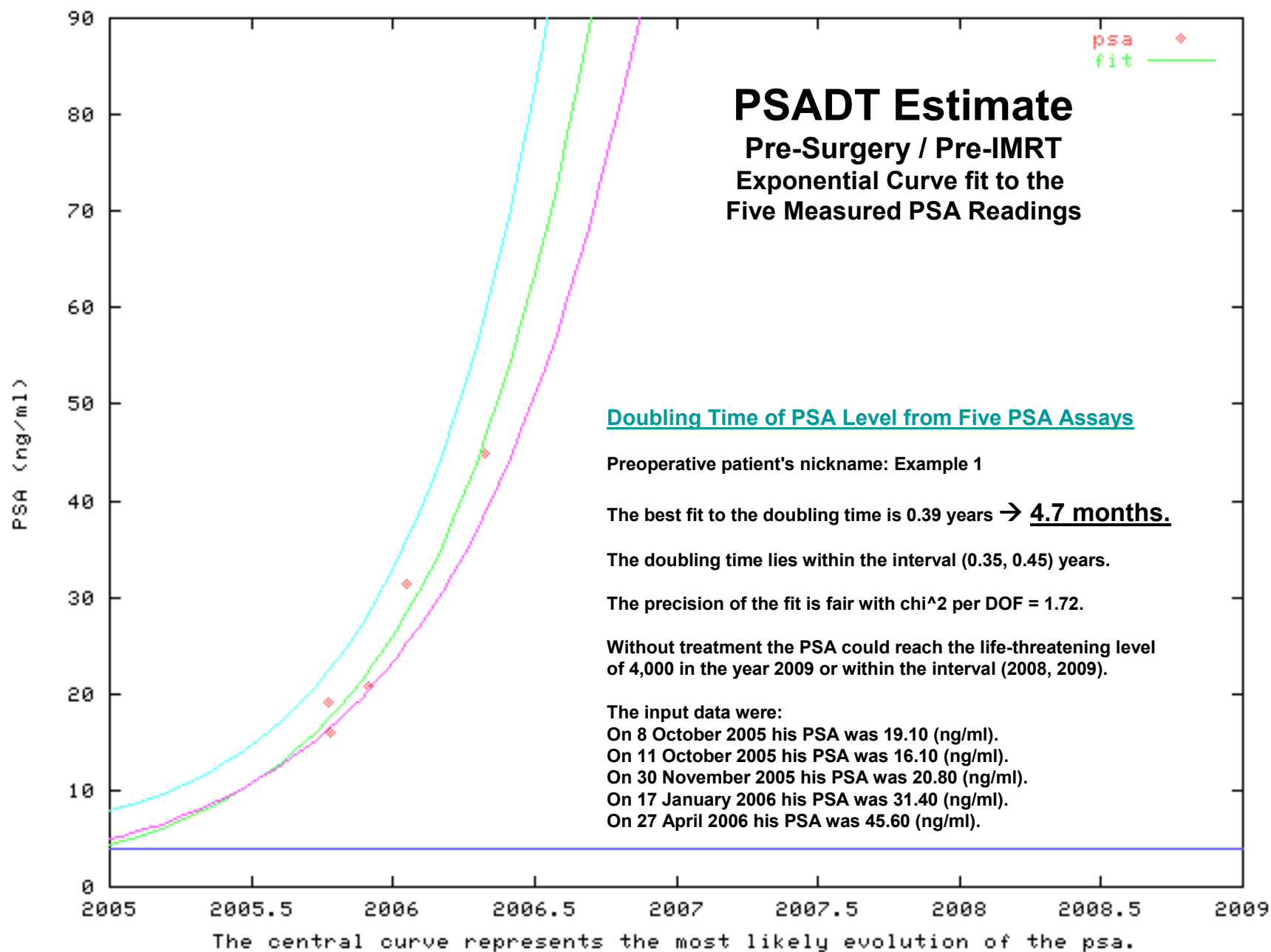
[Reference: Rising PSA in Nonmetastatic Prostate Cancer - Judd Moul and Stephen Freedland](#)

This example demonstrates the use of UltraSensitive PSA testing in early recurrence PC detection and intervention.

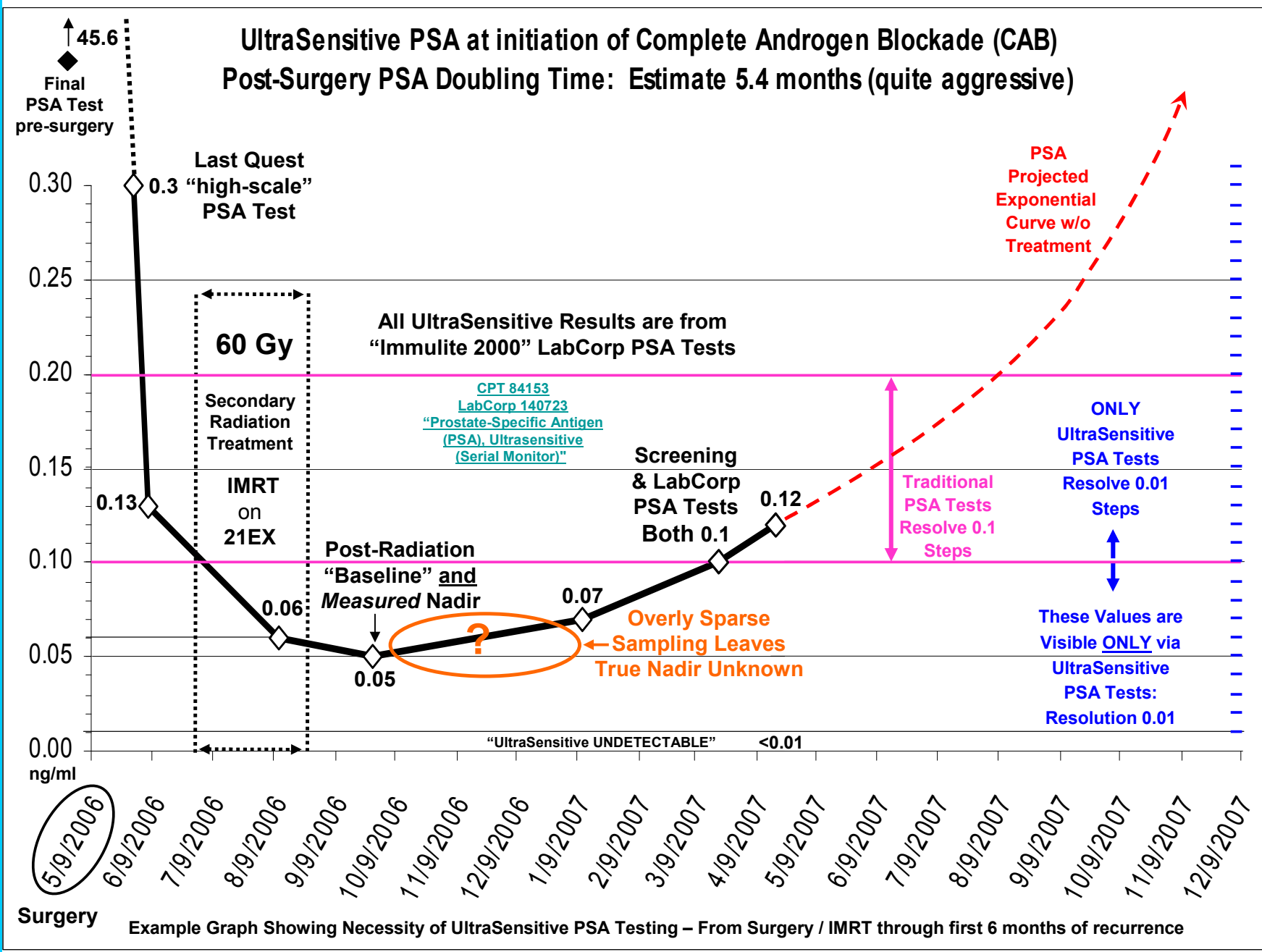
# Topic 001.1 - UltraSensitive PSA Testing Example – The Pre-Surgical History



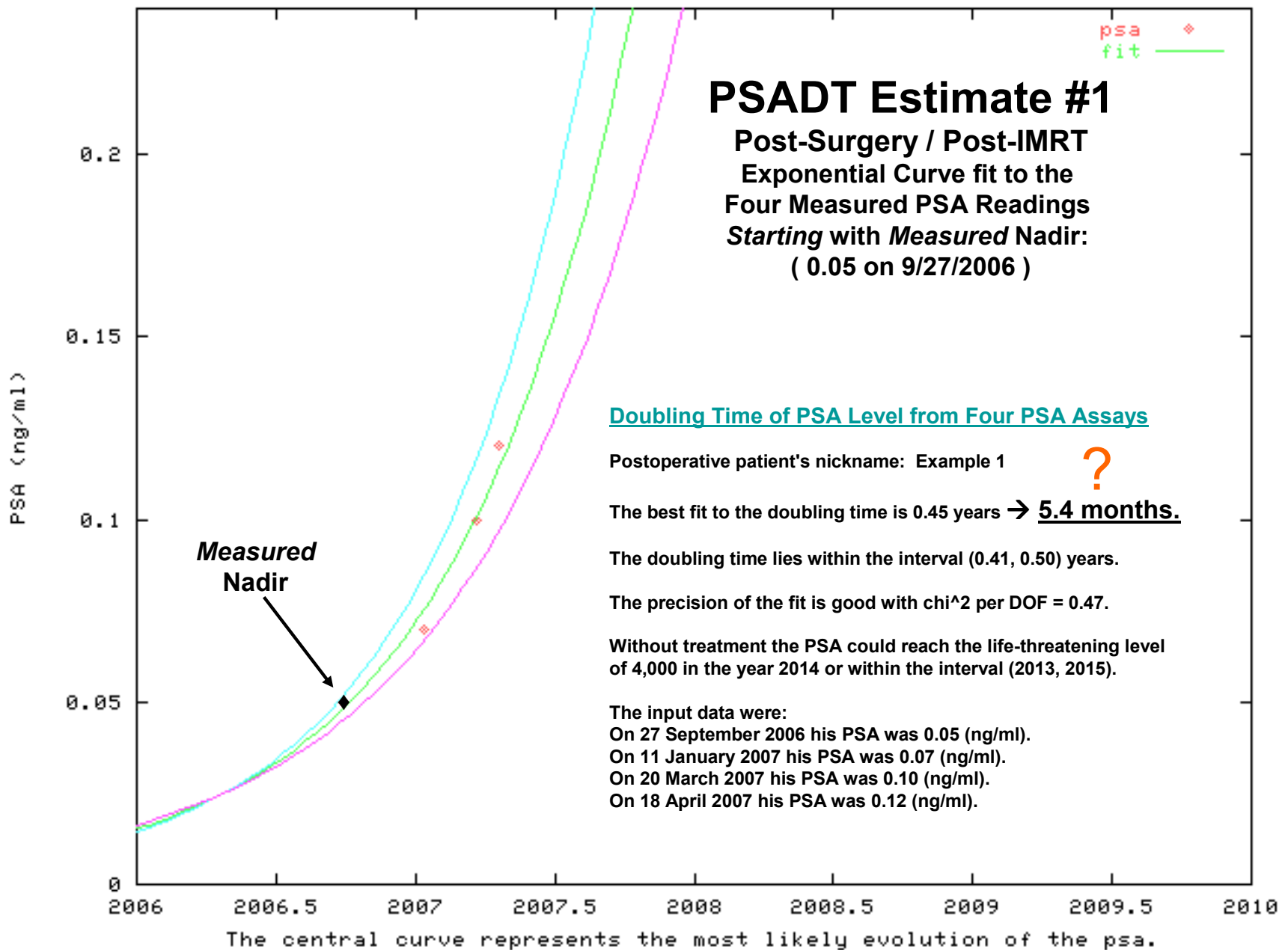
## Topic 001.2 - Pre-Surgery PSADT Estimated by Exponential Curve Fit



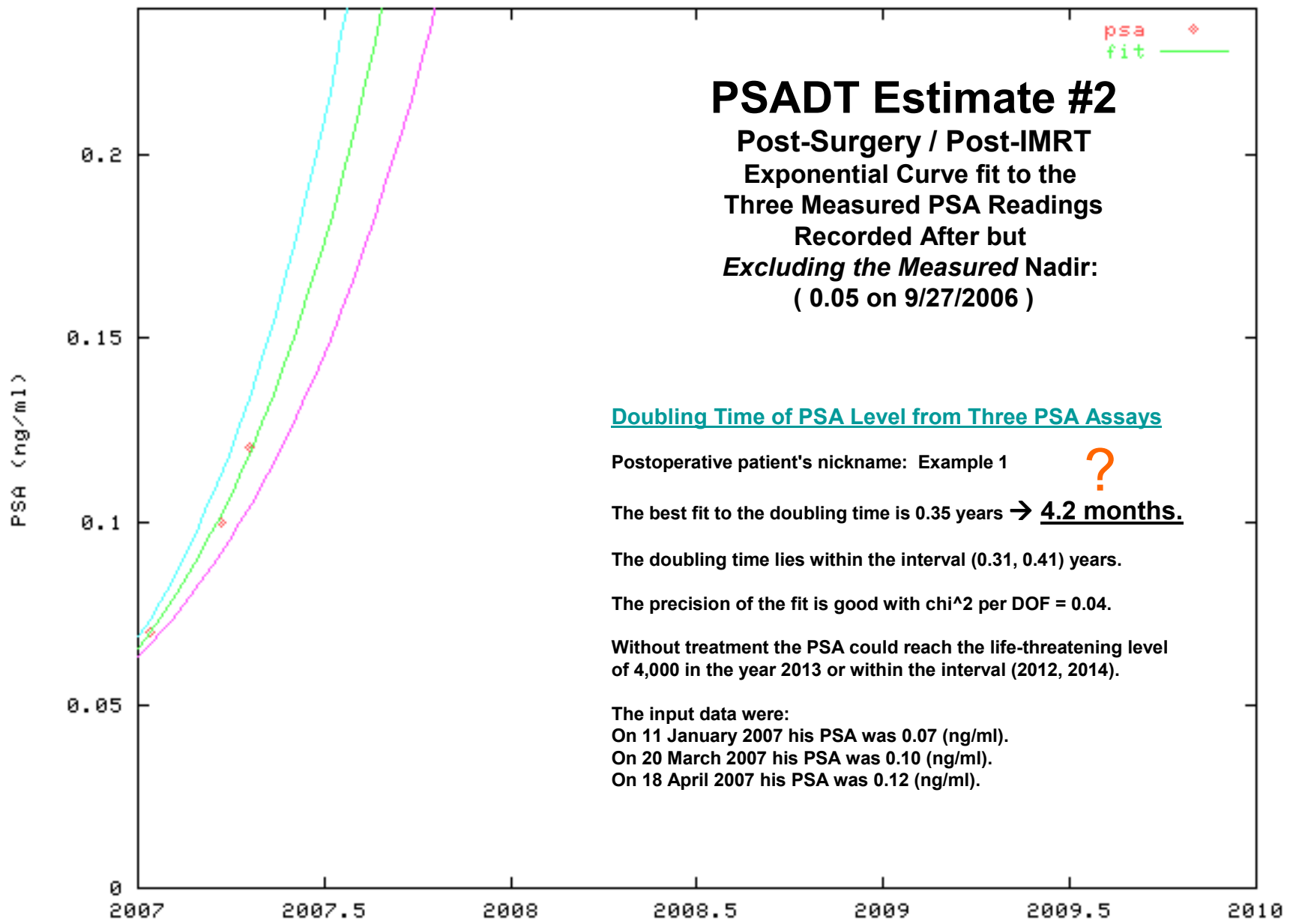
# Topic 001.3 - UltraSensitive PSA Testing – The Basics



# Topic 001.4 - Post-Treatment PSADT Initial Estimate by Exponential Curve Fit



## Topic 001.5 - Post-Treatment PSADT Estimated w/o Nadir



### Doubling Time of PSA Level from Three PSA Assays

Postoperative patient's nickname: Example 1



The best fit to the doubling time is 0.35 years → **4.2 months.**

The doubling time lies within the interval (0.31, 0.41) years.

The precision of the fit is good with  $\chi^2$  per DOF = 0.04.

Without treatment the PSA could reach the life-threatening level of 4,000 in the year 2013 or within the interval (2012, 2014).

The input data were:

On 11 January 2007 his PSA was 0.07 (ng/ml).

On 20 March 2007 his PSA was 0.10 (ng/ml).

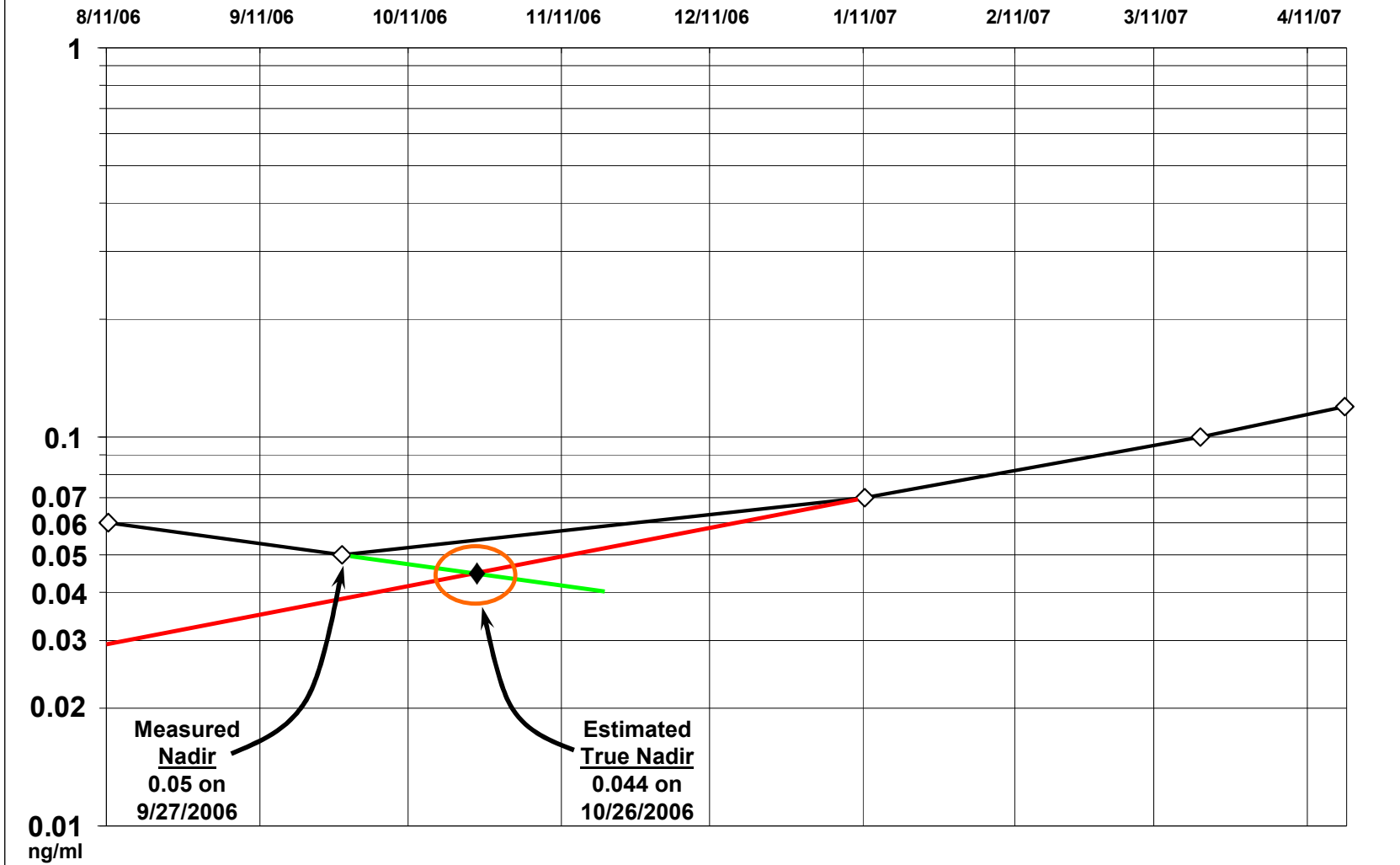
On 18 April 2007 his PSA was 0.12 (ng/ml).

The central curve represents the most likely evolution of the psa.

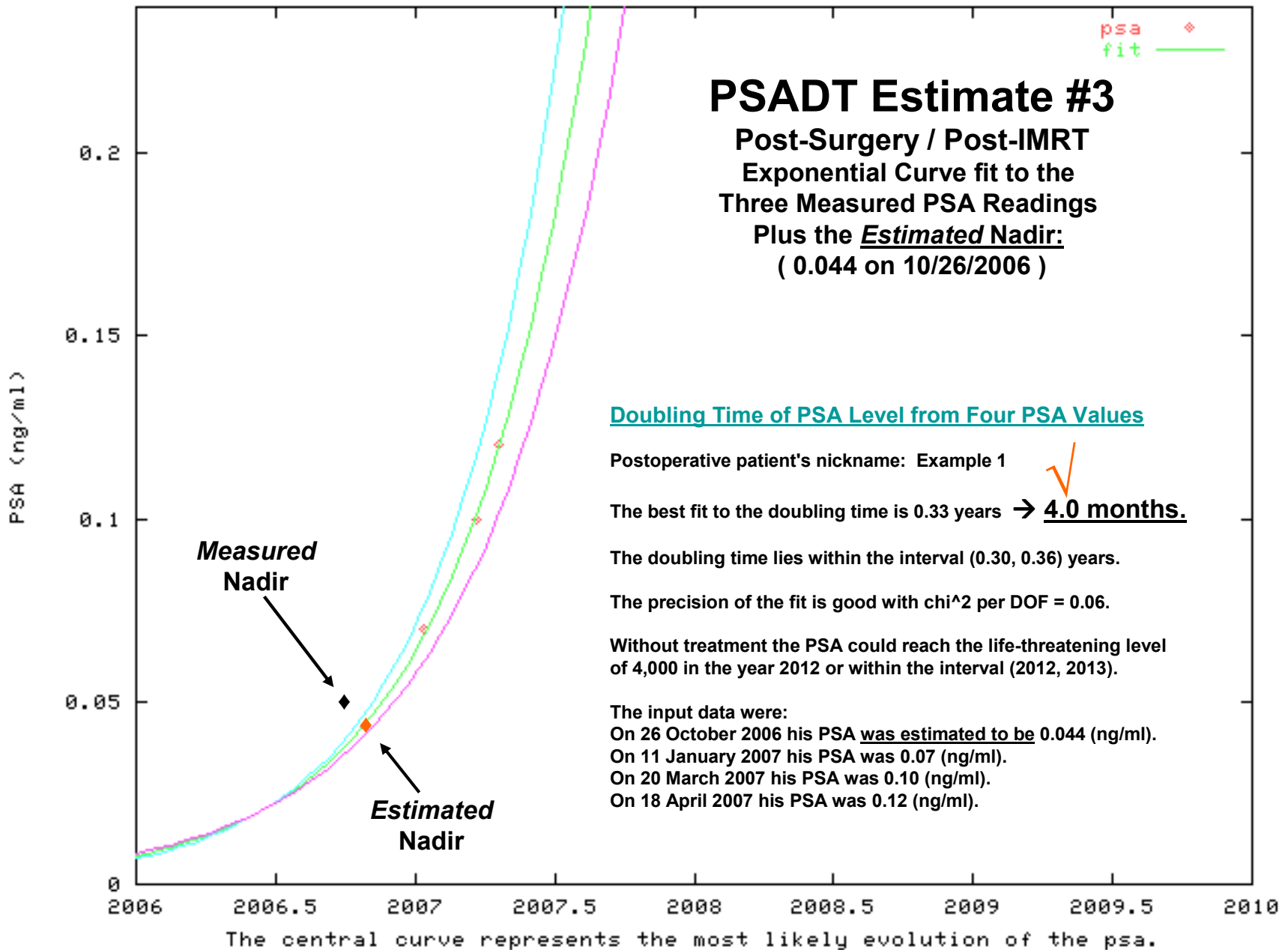
# Topic 001.6 - Estimating the True Nadir – Intercept of Decay and Growth Curves

## PSADT - Estimating True Nadir During Sparse Sampling Interval

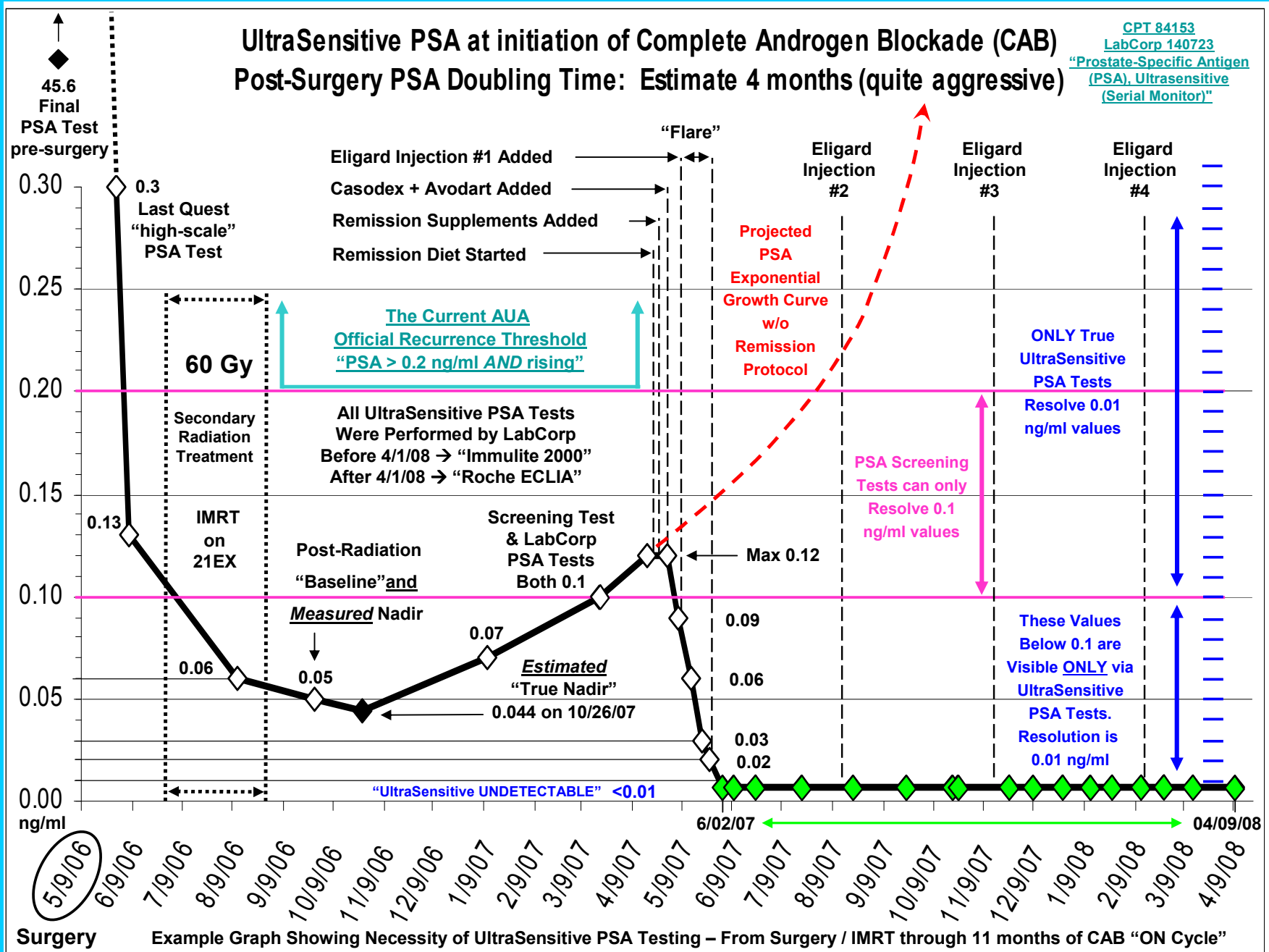
Best Estimate of the True Nadir is the Exponential Intersection of the **Decay Curve** with the **Reemergence Growth Curve**



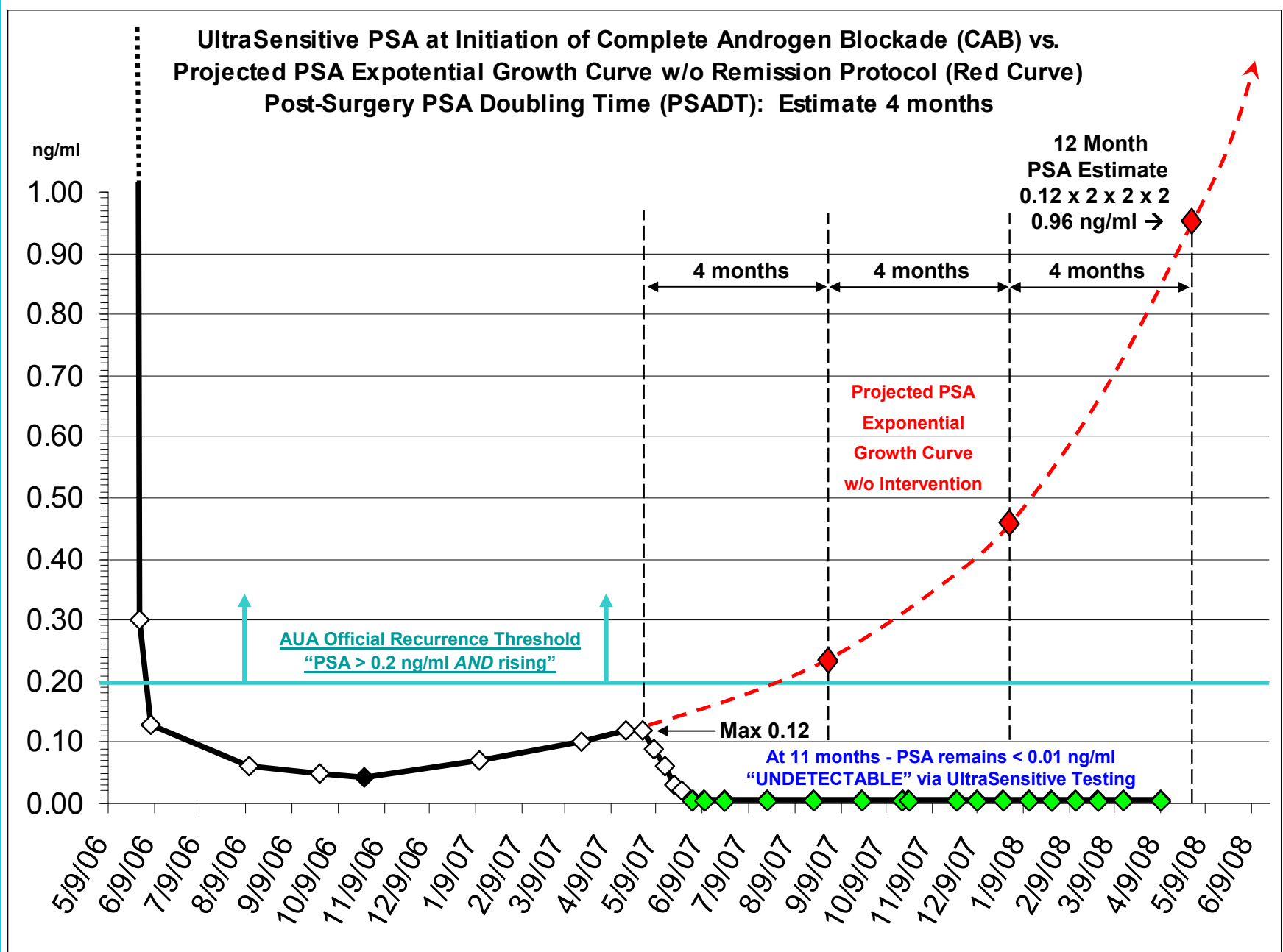
# Topic 001.7 - Post-Treatment PSADT Estimate Improved Using *Estimated Nadir*



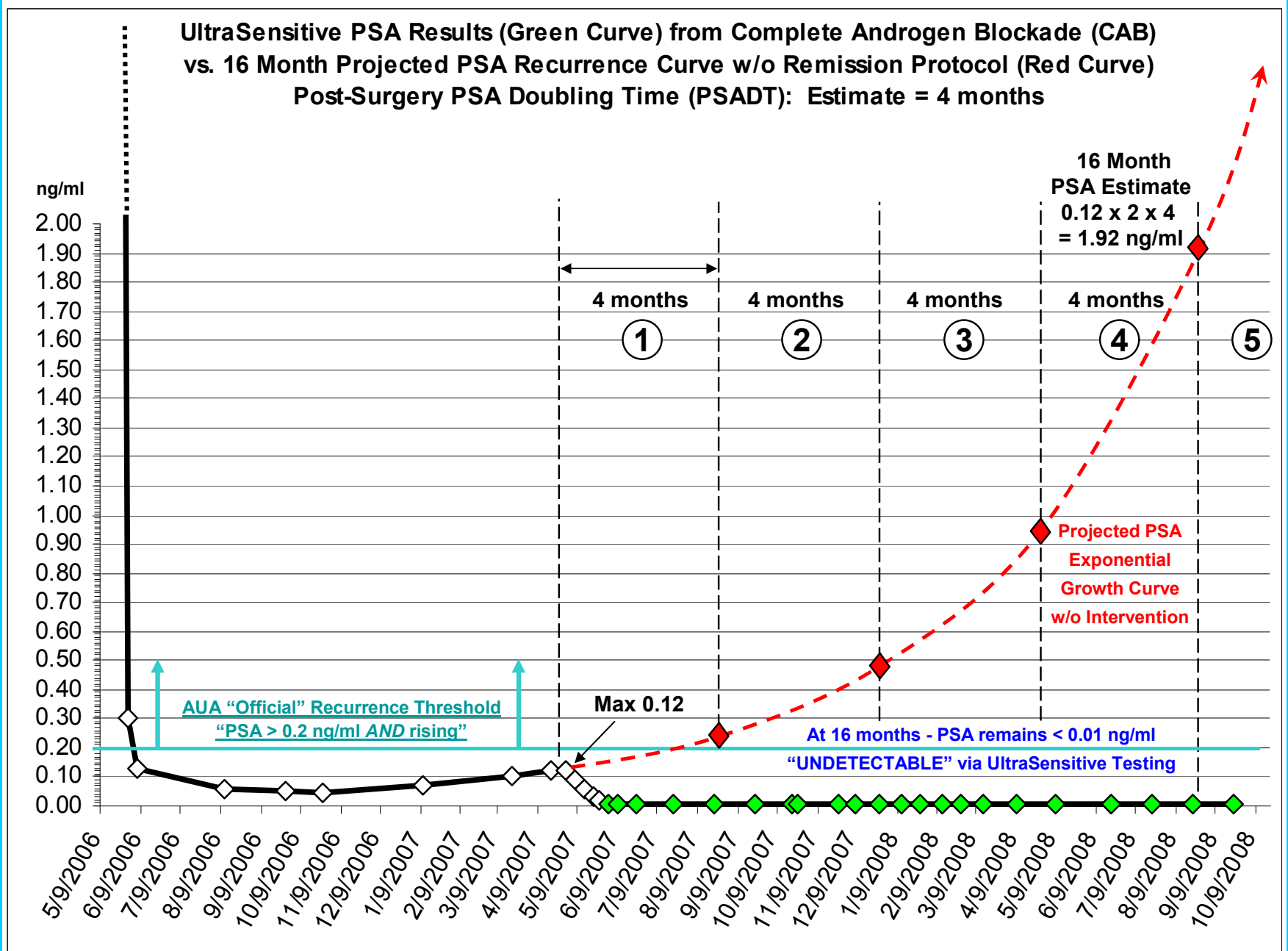
# Topic 001.8 - UltraSensitive PSA Testing – Remission Protocol Performance



# Topic 001.9 - UltraSensitive PSA Testing – Remission Protocol Performance



# Topic 001.10 - UltraSensitive PSA Testing – Remission Protocol Performance



# Topic 001.11 - UltraSensitive PSA Testing – Remission Protocol Performance

UltraSensitive PSA Results (Green Curve) from Complete Androgen Blockade (CAB)  
 vs. Projected PSA Recurrence Curve w/o Remission Protocol (Red Curve)  
 Post-Surgery PSA Doubling Time (PSADT): Estimate = 4 months

