# Second Survey of Prostate Specific Antigen Services in England

## Summary of Findings

The purpose of the second survey of PSA services was to identify the number and types of PSA tests that were being performed during the period 1st April 2003 to 31st March 2004. These results would then be compared to those identified in the first (baseline) survey to determine whether the change in policy on PSA testing and the introduction of the Prostate Cancer Risk Management Programme (PCRMP) had given rise to any changes to the service. The survey was sent in January 2005 to 220 English laboratories that participate in the UK NEQAS PSA scheme. Completed surveys were received from 118 laboratories giving a response rate of 54%. Of these laboratories 79 had participated in the previous survey and comparisons between the two years for these laboratories are shown as a separate subgroup.

### 1. Workload

The mean number of PSA tests being performed per laboratory has increased from 2000-01 to 2003-04 (Table 1). The total PSA workload in the 79 laboratories that participated in both surveys rose by 166973 tests or 39% in three years. If a year on year increase of approximately 5% is to be expected with all diagnostic tests, then the workload for these 79 laboratories might have been predicted to be in the region of 495742 in 2003-04, whereas the true figure was 595214.

Table 1 PSA workload for all laboratories participating in the two separate surveys and by subgroup

| | Number of laboratories | +Mean number of tests per laboratory | +Range | Total Number of tests |
|---|---|---|---|---|
| **Total PSA 2003-04** | 117/118 | 7313 | 74 to 23312 | 855638 |
| **Total PSA 2000-01** | 142/144 | 5544 | 3 to 17884 | 787301 |
| **Subgroup Total PSA 2003-04** | 79 | 7534 | 248 to 20665 | 595214 |
| **Subgroup Total PSA 2000-01** | 79 | 5421 | 250 to 16243 | 428241 |
| ***Free PSA 2003-04** | 18/118 | 1128 | 12 to 10777 | 20305 |

+Laboratories providing test *Excludes referred work

None of the participating laboratories in the current survey reported to be measuring complexed PSA.

Figures 1 and 2 illustrate the total PSA workloads recorded for all participating laboratories in the survey period 2003-04. A high proportion of the laboratories have workloads of up to 10000 total PSA tests a year.

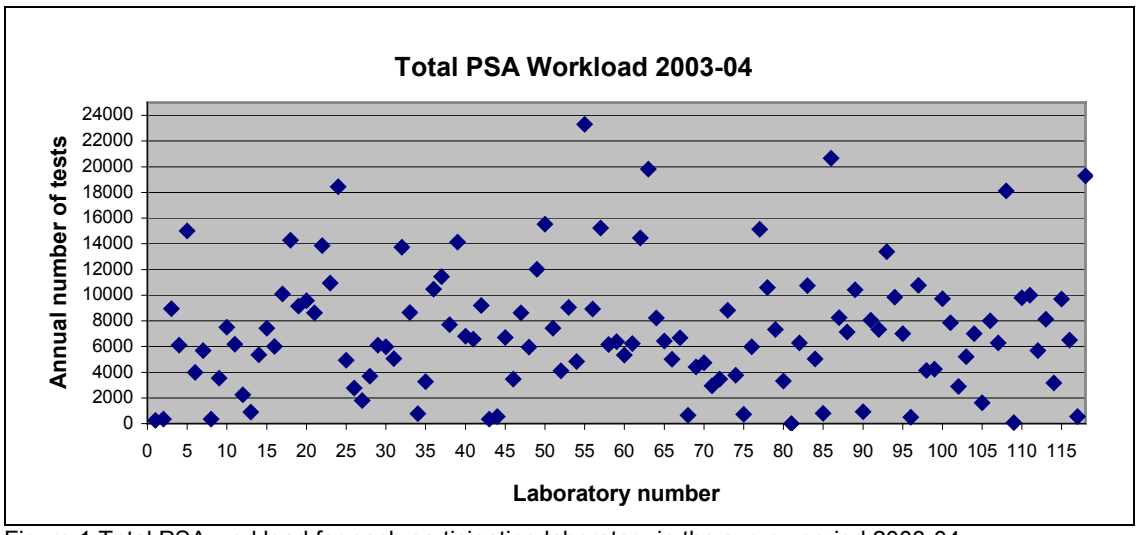


Figure 1 Total PSA workload for each participating laboratory in the survey period 2003-04.

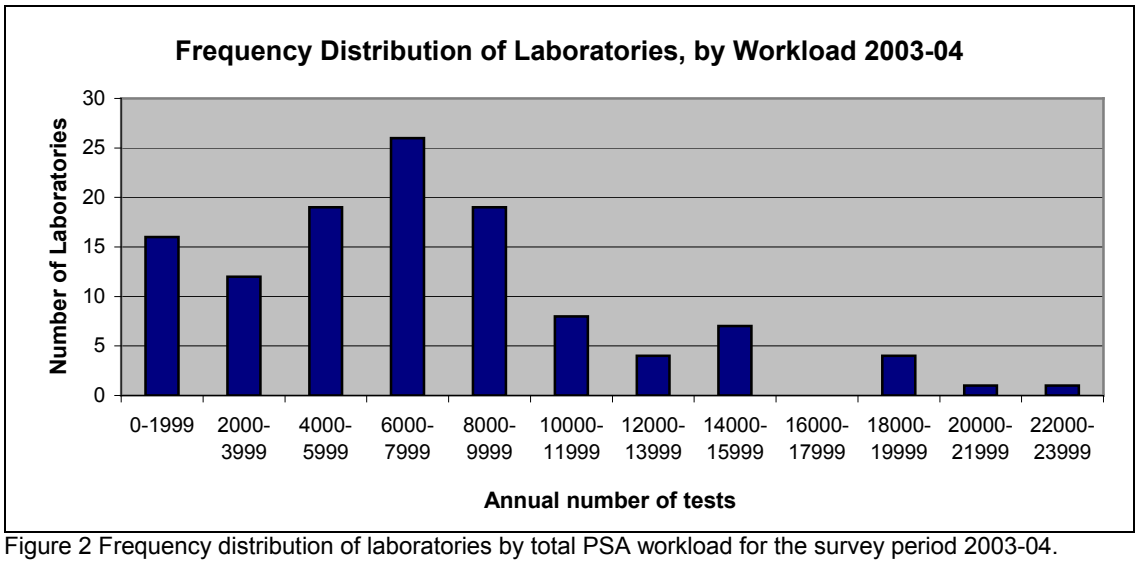


Figure 2 Frequency distribution of laboratories by total PSA workload for the survey period 2003-04.

Figures 3 and 4 illustrate the total PSA workloads for the 79 subgroup laboratories in each of the two surveys. It is clear to see the increased workload reported by the majority of these laboratories in 2003-04 from the area plot (figure 3). In addition the subset frequency distribution plot (figure 4) shows a clear shift to the right.

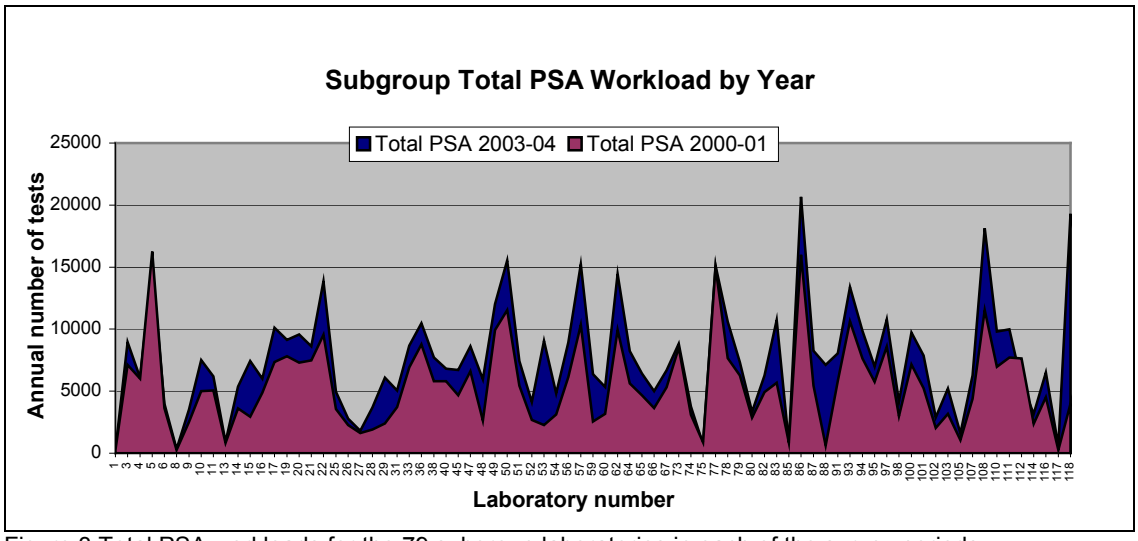


Figure 3 Total PSA workloads for the 79 subgroup laboratories in each of the survey periods.

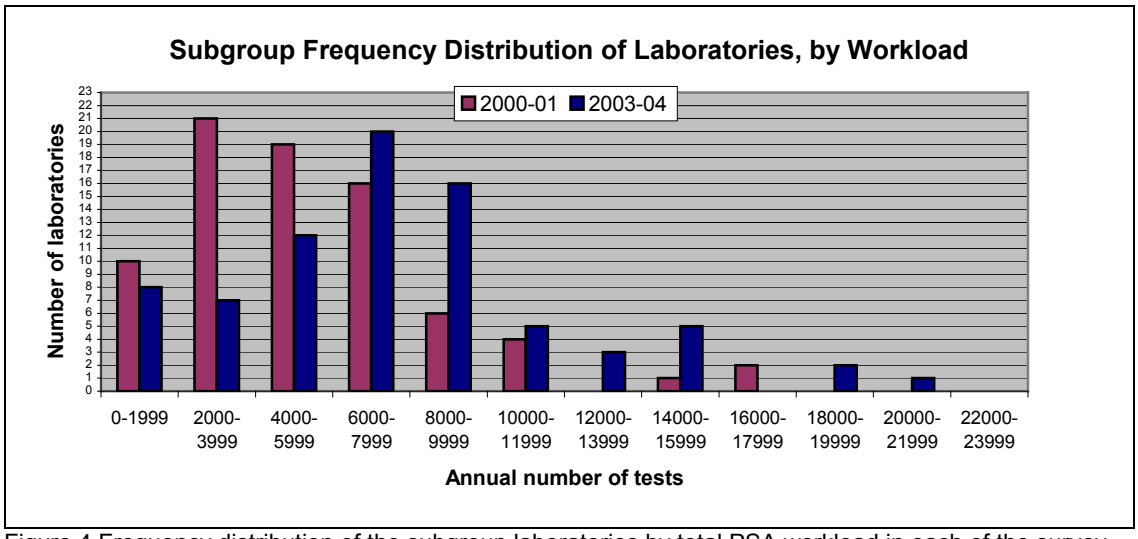


Figure 4 Frequency distribution of the subgroup laboratories by total PSA workload in each of the survey periods.

## 2. Origin of Samples

There has been a very small change in the origin of samples for PSA testing with a slightly higher proportion of the workload being received from GPs and a slightly lesser proportion from 'other' consultants, compared to three years ago (Tables 2 and 3).

Table 2 Origin of samples for PSA tests from all participating laboratories.

| | | %GP | %Urologist | %Other Consultants |
|---|---|---|---|---|
| **2003-04** | **Mean** | 51 | 33 | 15 |
| | **Range** | 0 to 95 | 3 to 90 | 0 to 55 |
| **2000-01** | **Mean** | 48 | 32 | 19 |
| | **Range** | 0 to 79 | 0 to 100 | 0 to 60 |

Table 3 Origin of samples for PSA tests from subgroup laboratories.

| | | %GP | %Urologist | %Other Consultants |
|---|---|---|---|---|
| **2003-04** | **Mean** | 52 | 31 | 16 |
| | **Range** | 0 to 78 | 7 to 95 | 0 to 55 |
| **2000-01** | **Mean** | 49 | 32 | 19 |
| | **Range** | 0 to 75 | 0 to 95 | 0 to 60 |

## 3. Turnaround Times

The average turnaround time for samples requiring PSA tests was in the majority of cases less than or equal to two calendar days, from the receipt of the sample to the availability of the result (Figure 5). Turnaround times reported as decimals were rounded to the nearest whole day.

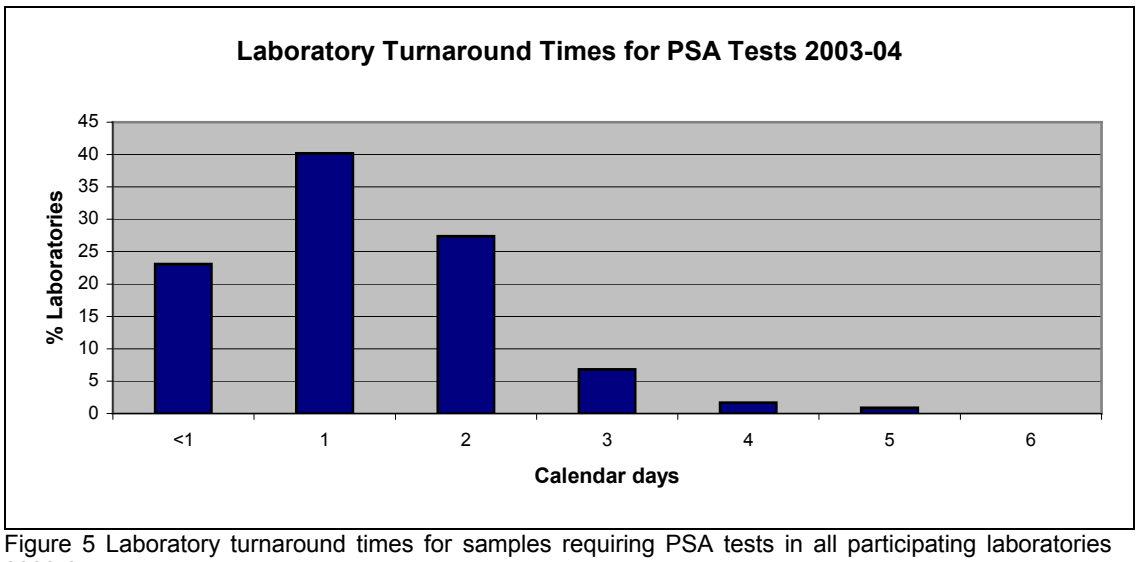


Figure 5 Laboratory turnaround times for samples requiring PSA tests in all participating laboratories 2003-04.

Turnaround times for samples requiring PSA tests in the subgroup laboratories did not increase with the greater workload and appear to have lessened slightly (Figure 6).

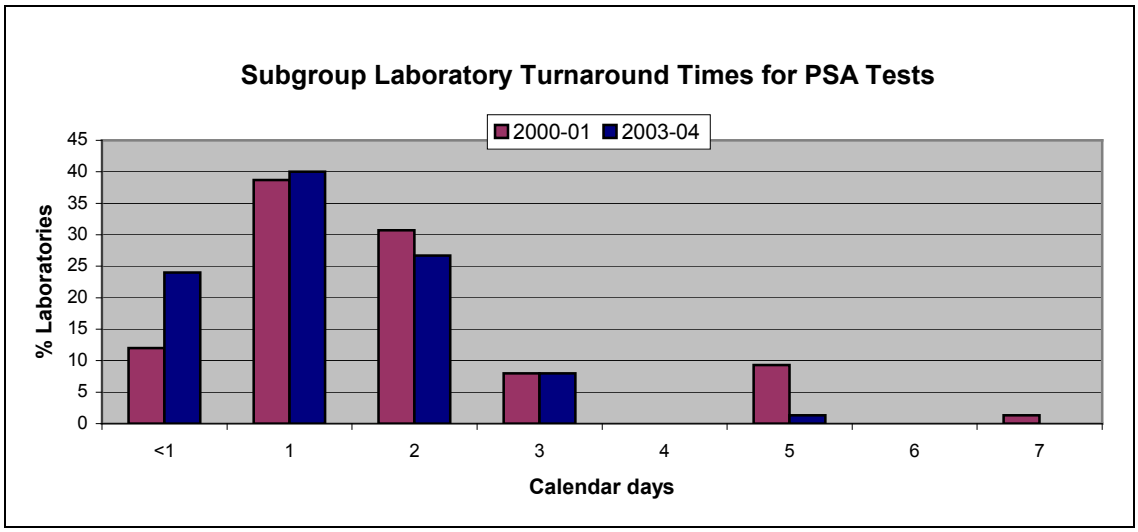


Figure 6 Laboratory turnaround times for samples requiring PSA tests for the subgroup laboratories in each survey.

## 4. Types of PSA Assay Employed

### Total PSA Assays

Information relating to the type of total PSA assay employed was provided by 99 of the 118 laboratories performing the test (Figure 7). Those assays considered acceptable to the PCRMP in terms of bias and molarity are shown in green (Roddam et al, 2006). Assays shown in yellow have borderline characteristics but are also acceptable, whereas assays in red are not acceptable. It has not been possible to assess assays shown in blue, due to the very small number of users nationally.

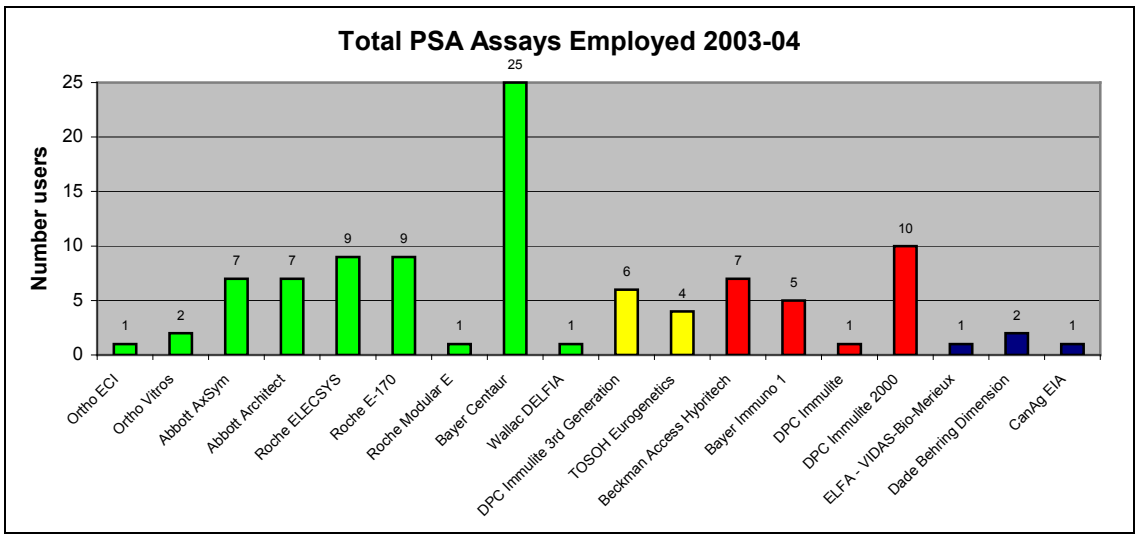


Figure 7 Total PSA assays employed during the period 2003-04. Green – Acceptable, Yellow – Borderline, Red – Unacceptable, Blue – Unknown.

Sixty-six of the subgroup laboratories provided information on the type of total PSA assay used in both surveys (Figure 8). Of these, 24 laboratories changed assays between the two survey periods. Eight laboratories moved from an assay with unacceptable/unknown characteristics to one with acceptable/borderline characteristics. Three laboratories changed from an acceptable assay to an unacceptable assay. One laboratory using an assay with borderline characteristics moved to an assay with unknown performance. Eight laboratories changed from an acceptable assay to another acceptable assay and four laboratories from an unacceptable assay to a further unacceptable assay.

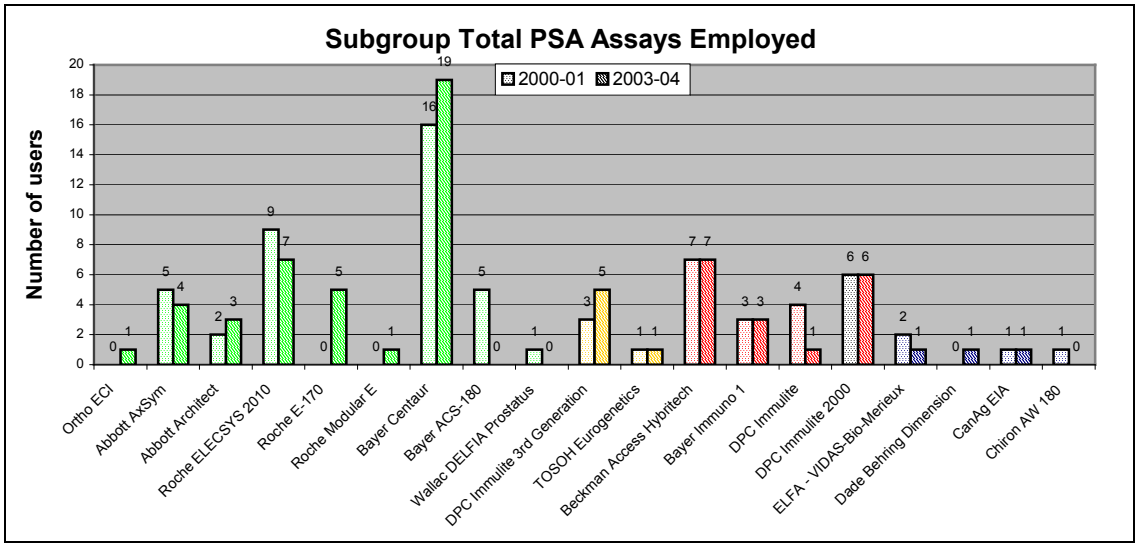

Figure 8 Total PSA assays employed by the subgroup laboratories in both surveys. Green – Acceptable, Yellow – Borderline, Red – Unacceptable, Blue – Unknown.

## Free PSA Assays

Free PSA assay types were reported by 17 laboratories performing the test (Table 4).

| Free PSA Assay | Number of users |
|---|---|
| Abbott methods | 3 |
| Beckman Access Hybritech | 3 |
| DPC Immulite 2000 | 4 |
| DPC Immulite 3rd Generation | 1 |
| Dade Behring Dimension Flex | 2 |
| Roche E170 | 2 |
| Roche Elecsys | 1 |
| Wallac Autodelfia | 1 |

Table 4 Free PSA assays employed during the period 2003-04.

## 5. Reference Ranges

### Survey Responses 2003-04

The total PSA reference ranges were provided by all 118 laboratories for the 2003-04 survey period. A single reference range was employed by 27 (23%) laboratories whilst 91 (77%) laboratories employed age related reference ranges.

Of the 27 laboratories using a single reference range 20 (16.9%) reported to be using the interval 0-4.0ng/ml.

The age related referral points outlined in the Department of Health Referral Guidance and adopted by the PCRMP are:

| Age | PSA ng/ml |
|---|---|
| 50-59 | $\geq$ 3.0 |
| 60-69 | $\geq$ 4.0 |
| 70 and over | >5 |

Of the 91 laboratories employing age related reference ranges 6 used ranges that directly equated to the guidance above, 21 used reference ranges that almost equated to the guidance with just one or two slight differences and 60 were using a different scheme. Four laboratories did not provide specific details of the ranges used.

### Subgroup Responses

Within the subgroup laboratories there has been a move towards the employment of age related reference ranges over a single reference range, however, the majority of laboratories do not follow the Department of Health Referral Guidance (Table 5).

Table 5 Subgroup reference ranges for both survey periods.

| | | 2000-01 | 2003-04 |
|---|---|---|---|
| **Age related reference range** | **PCRMP** | 0 | 4 |
| | **Nearly PCRMP** | 2 | 17 |
| | **Other** | 46 | 46 |
| **Single reference range** | | 28 | 12 |

There were a number of other age related reference ranges employed; the most commonly used scheme in both surveys is outlined below.

| Age | PSA (ng/ml) |
|---|---|
| 40-49 | 0-2.5 |
| 50-59 | 0-3.5 |
| 60-69 | 0-4.5 |
| 70-79 | 0-6.5 |

## 6. Source of Total PSA Reference Ranges

### Survey Responses 2003-04

The origin of the total PSA reference range employed was provided by 114 laboratories (Table 6). One resource was used by 82% of laboratories, whilst 18% used two or more resources to define their reference ranges.

Table 6 Origin of total PSA reference ranges for 2003-04.

| Source | Percentage of Laboratories using Source |
|---|---|
| DH Referral Guidance | 32 |
| Literature | 34 |
| Kit Insert | 34 |
| Local Data | 17 |
| Other | 5 |

### Subgroup Responses

Table 7 shows that just over a quarter of the subgroup laboratories are now taking note of the Department of health referral guidance and using this information to define/help define their total PSA reference ranges.

Table 7 Origin of total PSA reference ranges for the subgroup laboratories in both surveys.

| Source | Percentage of Laboratories using Source | |
|---|---|---|
| | 2000-01 | 2003-04 |
| DH Referral Guidance | 1 | 28 |
| Literature | 57 | 39 |
| Kit Insert | 38 | 23 |
| Local Data | 14 | 14 |
| Other | 10 | 6 |

### Reference

Roddam A W, Rimmer J, Nickerson C, Milford Ward A. Prostate Specific Antigen: Bias and Molarity of Commercial Assays for PSA in use in England. *Ann Clin Biochem* 2006; **43**: 35-48.